(iii) Based on this amount and the number of claims pending for the supplier, the carrier must determine and issue advance payments.

(iv) If historical data are not available or if backlogged claims cannot be identified, the carrier must determine and issue advance payments based on some other methodology approved by CMS.

(v) Advance payments can be made no more frequently than once every 2 weeks to a supplier.

(2) Generally, a supplier will not receive advance payments for more assigned claims than were paid, on a daily average, for the 90-day period before the system malfunction.

(3) A carrier must recover an advance payment by applying it against the amount due on the claim on which the advance was made. If the advance payment exceeds the Medicare payment amount, the carrier must apply the unadjusted balance of the advance payment against future Medicare payments due the supplier.

(4) In accordance with CMS instructions, a carrier must maintain a financial system of data in accordance with the Statement of Federal Financial Accounting Standards for tracking each advance payment and its recoupment.

(g) *Requirements for CMS.* (1) In accordance with the provisions of this section, CMS may determine that circumstances warrant the issuance of advance payments to all affected suppliers furnishing Part B services. CMS may waive the requirement in paragraph (e)(1) of this section as part of that determination.

(2) If adjusting Medicare payments fails to recover an advance payment, CMS may authorize the use of any other recoupment method available (for example, lump sum repayment or an extended repayment schedule) including, upon written notice from the carrier to the supplier, converting any unpaid balances of advance payments to overpayments. Overpayments are recovered in accordance with part 401, subpart F of this chapter concerning claims collection and compromise and part 405, subpart C of this chapter concerning recovery of overpayments.

(h) *Prompt payment interest.* An advance payment is a "payment" under section 1842(c)(2)(C) of the Act for purposes of meeting the time limit for the payment of clean claims, to the extent of the advance payment.

(i) *Notice, review, and appeal rights.* (1) The decision to advance payments and the determination of the amount of any advance payment are committed to CMS's discretion and are not subject to review or appeal.

(2) The carrier must notify the supplier receiving an advance payment about the amounts advanced and recouped and how any Medicare payment amounts have been adjusted.

(3) The supplier may request an administrative review from the carrier if it believes the carrier's reconciliation of the amounts advanced and recouped is incorrectly computed. If a review is requested, the carrier must provide a written explanation of the adjustments.

(4) The review and explanation described in paragraph (i)(3) of this section is separate from a supplier's right to appeal the amount and computation of benefits paid on the claim, as provided at part 405, subpart H of this chapter. The carrier's reconciliation of amounts advanced and recouped is not an initial determination as defined at §405.803 of this chapter, and any written explanation of a reconciliation is not subject to further administrative review.

[61 FR 49275, Sept. 19, 1996]

PART 422—MEDICARE+CHOICE PROGRAM

Subpart A—General Provisions

Sec.

Subpart B—Eligibility, Election, and Enrollment

Subpart I—Organization Compliance With State Law and Preemption by Federal Law

Subpart J [Reserved]

Subpart K—Contracts With Medicare+Choice Organizations

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

Subpart M—Grievances, Organization Determinations and Appeals

Subpart N—Medicare Contract Determinations and Appeals

Subpart O—Intermediate Sanctions

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 63 FR 18134, Apr. 14, 1998, unless otherwise noted.

Subpart A—General Provisions

SOURCE: 63 FR 35068, June 26, 1998, unless otherwise noted.

§422.1 Basis and scope.

(a) *Basis.* This part is based on the indicated provisions of the following sections of the Act:

1851—Eligibility, election, and enrollment.
1852—Benefits and beneficiary protections.
1853—Payments to Medicare+Choice (M+C) organizations.
1854—Premiums.
1855—Organization, licensure, and solvency of M+C organizations.
1856—Standards.
1857—Contract requirements.
1859—Definitions; enrollment restriction for certain M+C plans.

(b) *Scope.* This part establishes standards and sets forth the requirements, limitations, and procedures for Medicare services furnished, or paid for, by Medicare+Choice organizations through Medicare+Choice plans.

§422.2 Definitions.

As used in this part—

ACR stands for adjusted community rate.

Additional benefits are health care services not covered by Medicare, reductions in premiums or cost-sharing for Medicare covered services, and reductions in the Medicare beneficiary's standard Part B premium, funded from adjusted excess amounts as calculated in the ACR.

Adjusted community rate (ACR) is the equivalent of the maximum amount allowed under §422.310.

Arrangement means a written agreement between an M+C organization and a provider or provider network, under which—

(1) The provider or provider network agrees to furnish for a specific M+C plan(s) specified services to the organization's M+C enrollees;

(2) The organization retains responsibilities for the services; and

(3) Medicare payment to the organization discharges the enrollee's obligation to pay for the services.

Balance billing generally refers to an amount billed by a provider that represents the difference between the amount the provider charges an individual for a service and the sum of the amount the individual's health insurer (for example, the original Medicare program) will pay for the service plus any cost-sharing by the individual.

Basic benefits means all Medicare-covered benefits (except hospice services) and additional benefits.

Benefits are health care services that are intended to maintain or improve the health status of enrollees, for which the M+C organization incurs a cost or liability under an M+C plan (not solely an administrative processing cost). Benefits are submitted and approved through the ACR process.

Coinsurance is a fixed percentage of the total amount paid for a health care service that can be charged to an M+C enrollee on a per-service basis.

Copayment is a fixed amount that can be charged to an M+C plan enrollee on a per-service basis.

Cost-sharing includes deductibles, coinsurance, and copayments.

Licensed by the State as a risk-bearing entity means the entity is licensed or otherwise authorized by the State to assume risk for offering health insurance or health benefits coverage, such that the entity is authorized to accept

prepaid capitation for providing, arranging, or paying for comprehensive health services under an M+C contract.

M+C stands for Medicare+Choice.

M+C eligible individual means an individual who meets the requirements of § 422.50.

M+C organization means a public or private entity organized and licensed by a State as a risk-bearing entity (with the exception of provider-sponsored organizations receiving waivers) that is certified by CMS as meeting the M+C contract requirements.

M+C plan means health benefits coverage offered under a policy or contract by an M+C organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the M+C plan (or in individual segments of a service area, under § 422.304(b)(2)).

M+C plan enrollee is an M+C eligible individual who has elected an M+C plan offered by an M+C organization.

Mandatory supplemental benefits are health services not covered by Medicare that an M+C enrollee must purchase as part of an M+C plan that are paid for in full, directly by (or on behalf of) Medicare enrollees, in the form of premiums or cost-sharing.

MSA stands for medical savings account.

MSA trustee means a person or business with which an enrollee establishes an M+C MSA. A trustee may be a bank, an insurance company, or any other entity that—

(1) Is approved by the Internal Revenue Service to be a trustee or custodian of an individual retirement account (IRA); and

(2) Meets the requirements of § 422.262(b).

National coverage determination (NCD) means a national policy determination regarding the coverage status of a particular service that CMS makes under section 1862(a)(1) of the Act, and publishes as a FEDERAL REGISTER notice or CMS ruling. (The term does not include coverage changes mandated by statute.)

Optional supplemental benefits are health services not covered by Medicare that are purchased at the option of the M+C enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost-sharing. These services may be grouped or offered individually.

Original Medicare means health insurance available under Medicare Part A and Part B through the traditional fee-for service payment system.

Point of service (POS) is a benefit option that an M+C coordinated care plan can offer to its Medicare enrollees as an additional, mandatory supplemental, or optional supplemental benefit. Under the POS benefit option, the M+C plan allows members the option of receiving specified services outside of the M+C plan's provider network. In return for this flexibility, members typically have higher cost-sharing requirements for services received and, where offered as a mandatory or optional supplemental benefit, may also be charged a premium for the POS benefit option.

Provider means—

(1) Any individual who is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the State; and

(2) Any entity that is engaged in the delivery of health care services in a State and is licensed or certified to deliver those services if such licensing or certification is required by State law or regulation.

Provider network means the providers with which an M+C organization contracts or makes arrangements to furnish covered health care services to Medicare enrollees under an M+C coordinated care or network MSA plan.

Religious and fraternal benefit (RFB) society means an organization that—

(1) Is described in section 501(c)(8) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of that Act; and

(2) Is affiliated with, carries out the tenets of, and shares a religious bond with, a church or convention or association of churches or an affiliated group of churches.

RFB plan means an M+C plan that is offered by an RFB society.

Service area means a geographic area approved by CMS within which an M+C-eligible individual may enroll in a particular M+C plan offered by an M+C

organization. Each M+C plan must be available to all M+C-eligible individuals within the plan's service area. In deciding whether to approve an M+C plan's proposed service area, CMS considers the following criteria:

(1) Whether the area meets the "county integrity rule" that a service area generally consists of a full county or counties. However, CMS may approve a service area that includes a portion of a county if it determines that the "partial county" area is necessary, nondiscriminatory, and in the best interests of the beneficiaries.

(2) The extent to which the proposed services area mirrors service areas of existing commercial health care plans or M+C plans offered by the organization.

(3) For M+C coordinated care plans and network M+C MSA plans, whether the contracting provider network meets the access and availability standards set forth in §422.112. Although not all contracting providers must be located within the plan's service area, CMS must determine that all services covered under the plan are accessible from the service area.

(4) For non-network M+C MSA plans, CMS may approve single county non-network M+C MSA plans even if the M+C organization's commercial plans have multiple county service areas.

[63 FR 35068, June 26, 1998, as amended at 65 FR 40314, June 29, 2000; 68 FR 50855, Aug. 22, 2003]

§422.4 Types of M+C plans.

(a) *General rule.* An M+C plan may be a coordinated care plan, a combination of an M+C MSA plan and a contribution into an M+C MSA established in accordance with §422.262, or an M+C private fee-for-service plan.

(1) *A coordinated care plan.* A coordinated care plan is a plan that includes a network of providers that are under contract or arrangement with the organization to deliver the benefit package approved by CMS.

(i) The network is approved by CMS to ensure that all applicable requirements are met, including access and availability, service area, and quality.

(ii) Coordinated care plans may include mechanisms to control utilization, such as referrals from a gatekeeper for an enrollee to receive services within the plan, and financial arrangements that offer incentives to providers to furnish high quality and cost-effective care.

(iii) Coordinated care plans include plans offered by health maintenance organizations (HMOs), provider-sponsored organizations (PSOs), preferred provider organizations (PPOs) as specified in paragraph (a)(1)(iv) of this section, RFBs, and other network plans (except network MSA plans).

(iv) A PPO plan is a plan that has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and is offered by an organization that is not licensed or organized under State law as an HMO.

(2) *A combination of an M+C MSA plan and a contribution into the M+C MSA established in accordance with §422.262.* (i) *M+C MSA plan* means a plan that—

(A) Pays at least for the services described in §422.101, after the enrollee has incurred countable expenses (as specified in the plan) equal in amount to the annual deductible specified in §422.103(d); and

(B) Meets all other applicable requirements of this part.

(ii) An M+C MSA plan may be either a network plan or a non-network plan.

(A) *M+C network MSA plan* means an MSA plan under which enrollees must receive services through a defined provider network that is approved by CMS to ensure that all applicable requirements are met, including access and availability, service area, and quality.

(B) *M+C non-network MSA plan* means an MSA plan under which enrollees are not required to receive services through a provider network.

(iii) *M+C MSA* means a trust or custodial account—

(A) That is established in conjunction with an MSA plan for the purpose of paying the qualified expenses of the account holder; and

(B) Into which no deposits are made other than contributions by CMS under the M+C program, or a trustee-to-

trustee transfer or rollover from another M+C MSA of the same account holder, in accordance with the requirements of sections 138 and 220 of the Internal Revenue Code.

(3) *M+C private fee-for-service plan.* An M+C private fee-for-service plan is an M+C plan that—

(i) Pays providers of services at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk;

(ii) Does not vary the rates for a provider based on the utilization of that provider's services; and

(iii) Does not restrict enrollees' choices among providers that are lawfully authorized to provide services and agree to accept the plan's terms and conditions of payment.

(b) *Multiple plans.* Under its contract, an M+C organization may offer multiple plans, regardless of type, provided that the M+C organization is licensed or approved under State law to provide those types of plans (or, in the case of a PSO plan, has received from CMS a waiver of the State licensing requirement). If an M+C organization has received a waiver for the licensing requirement to offer a PSO plan, that waiver does not apply to the licensing requirement for any other type of M+C plan.

[63 FR 35068, June 26, 1998, as amended at 65 FR 40315, June 29, 2000]

§ 422.6 Application requirements.

(a) *Scope.* This section sets forth application requirements for entities that seek a contract as an M+C organization offering an M+C plan.

(b) *Completion of an application.* (1) In order to obtain a determination on whether it meets the requirements to become an M+C organization and is qualified to provide a particular type of M+C plan, an entity, or an individual authorized to act for the entity (the applicant) must complete a certified application, in the form and manner required by CMS, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards applicable to M+C plans, and is authorized by the State to accept prepaid capitation for providing, arranging, or paying for the comprehensive health care services to be offered under the M+C contract; or

(ii) Federal waiver as described in subpart H of this part.

(2) The authorized individual must describe thoroughly how the entity and M+C plan meet, or will meet, the requirements described in this part.

(c) *Responsibility for making determinations.* CMS is responsible for determining whether an entity qualifies as an M+C organization and whether proposed M+C plans meet the requirements of this part.

(d) *Resubmittal of application.* An application that has been denied by CMS may not be resubmitted for 4 months after the date of the notice from CMS denying the application.

(e) *Disclosure of application information under the Freedom of Information Act.* An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of exceptions provided in 45 CFR part 5 (the Department's regulations providing exceptions to disclosure), should label the material "privileged" and include an explanation of the applicability of an exception described in 45 CFR part 5.

§ 422.8 Evaluation and determination procedures.

(a) *Basis for evaluation and determination.* (1) CMS evaluates an application for an M+C contract on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits, public hearings, and any other appropriate procedures.

(2) If the application is incomplete, CMS notifies the contract applicant and allows 60 days from the date of the notice for the contract applicant to furnish the missing information.

(3) After evaluating all relevant information, CMS determines whether the contract applicant's application meets the applicable requirements of § 422.6.

(b) *Use of information from a prior contracting period.* If an M+C organization, HMO, competitive medical plan, or

health care prepayment plan has failed to comply with the terms of a previous year's contract with CMS under title XVIII of the Act, or has failed to complete a corrective action plan during the term of the contract, CMS may deny an application from a contract applicant based on the contract applicant's failure to comply with that prior contract with CMS even if the contract applicant meets all of the current requirements.

(c) *Notice of determination.* CMS notifies each applicant that applies for an M+C contract under this part of its determination and the basis for the determination. The determination may be approval, intent to deny, or denial.

(d) *Approval of application.* If CMS approves the application, it gives written notice to the contract applicant, indicating that it meets the requirements for an M+C contract.

(e) *Intent to deny.* (1) If CMS finds that the contract applicant does not appear to meet the requirements for an M+C organization and appears to be able to meet those requirements within 60 days, CMS gives the contract applicant notice of intent to deny the application for an M+C contract and a summary of the basis for this preliminary finding.

(2) Within 60 days from the date of the notice, the contract applicant may respond in writing to the issues or other matters that were the basis for CMS's preliminary finding and may revise its application to remedy any defects CMS identified.

(f) *Denial of application.* If CMS denies the application, it gives written notice to the contract applicant indicating—

(1) That the contract applicant does not meet the contract requirements under part C of title XVIII of the Act;

(2) The reasons why the contract applicant does not meet the contract requirements; and

(3) The contract applicant's right to request reconsideration in accordance with the procedures specified in subpart N of this part.

(g) *Oversight of continuing compliance.* (1) CMS oversees an M+C organization's continued compliance with the requirements for an M+C organization.

(2) If an M+C organization no longer meets those requirements, CMS terminates the contract in accordance with § 422.510.

[65 FR 40315, June 29, 2000]

§ 422.10 Cost-sharing in enrollment-related costs (M+C user fee).

(a) *Basis and scope.* This section implements that portion of section 1857 of the Act that pertains to cost-sharing in enrollment-related costs. It sets forth the procedures that CMS follows to determine the aggregate annual "user fee" to be contributed by M+C organizations and to assess the required user fees for M+C plans offered by M+C organizations.

(b) *Purpose of assessment.* Section 1857(e)(2) of the Act authorizes CMS to charge and collect from each M+C plan offered by an M+C organization its pro rate share of fees for administering section 1851 of the Act, relating to dissemination of enrollment information; and section 4360 of the Omnibus Budget Reconciliation Act of 1990, relating to the health insurance counseling and assistance program.

(c) *Applicability.* The fee assessment also applies to those demonstrations for which enrollment is effected or coordinated under section 1851 of the Act.

(d) *Collection of fees.* (1) *Timing of collection.* CMS collects the fees over 9 consecutive months beginning with January of each fiscal year.

(2) *Amount to be collected.* The aggregate amount of fees for a fiscal year is the lesser of—

(i) The estimated costs to be incurred by CMS in that fiscal year to carry out the activities described in paragraph (b) of this section; or

(ii) For fiscal year 2000, $100 million and for fiscal year 2001 and each succeeding year, the M+C portion (as defined in paragraph (e) of this section) of $100 million.

(e) *M+C portion.* In this section, the term "M+C portion" means, for a fiscal year, the ratio, as estimated by the Secretary of the average number of individuals enrolled in M+C plans during the fiscal year to the average number of individuals entitled to benefits under part A, and enrolled under part B, during the fiscal year.

(f) *Assessment methodology.* (1) The amount of the M+C portion of the user fee each M+C organization must pay is

assessed as a percentage of the total Medicare payments to each organization. CMS determines this percentage rate using the following formula:

A times B divided by C where—
A is the total estimated January payments to all organizations subject to the assessment;
B is the 9-month (January through September) assessment period; and
C is the total fiscal year M+C user fee assessment amount determined in accordance with paragraph (d)(2) of this section.

(2) CMS determines each organization's pro rata share of the annual fee on the basis of the organization's calculated monthly payment amount during the 9 consecutive months beginning with January. CMS calculates each organization's monthly pro rata share by multiplying the established percentage rate by the total monthly calculated Medicare payment amount to the organization as recorded in CMS's payment system on the first day of the month.

(3) CMS deducts the organization's fee from the amount of Federal funds otherwise payable to the organization for that month under the M+C program.

(4) If assessments reach the amount authorized for the year before the end of September, CMS discontinues assessment.

(5) If there are delays in determining the amount of the annual aggregate fees specified in paragraph (d)(2) of this section, or the fee percentage rate specified in paragraph (f)(2), CMS may adjust the assessment time period and the fee percentage amount.

[65 FR 40315, June 29, 2000]

Subpart B—Eligibility, Election, and Enrollment

SOURCE: 63 FR 35071, June 26, 1998, unless otherwise noted.

§ 422.50 Eligibility to elect an M+C plan.

(a) An individual is eligible to elect an M+C plan if he or she—

(1) Is entitled to Medicare under Part A and enrolled in Part B (except that an individual entitled only to Part B and who was enrolled in an HMO or CMP with a risk contract under part 417 of this chapter on December 31, 1998 may continue to be enrolled in the M+C organization as an M+C plan enrollee);

(2) Has not been medically determined to have end-stage renal disease, except that—

(i) An individual who develops end-stage renal disease while enrolled in an M+C plan or in a health plan offered by the M+C organization is eligible to elect an M+C plan offered by that organization; and

(ii) An individual with end-stage renal disease whose enrollment in an M+C plan was terminated or discontinued after December 31, 1998, because CMS or the M+C organization terminated the M+C organization's contract for the plan or discontinued the plan in the area in which the individual resides, is eligible to elect another M+C plan. If the plan so elected is later terminated or discontinued in the area in which the individual resides, he or she may elect another M+C plan.

(3) Meets either of the following residency requirements:

(i) Resides in the service area of the M+C plan.

(ii) Resides outside of the service area of the M+C plan and is enrolled in a health plan offered by the M+C organization during the month immediately preceding the month in which the individual is entitled to both Medicare Part A and Part B, provided that an M+C organization chooses to offer this option and that CMS determines that all applicable M+C access requirements of § 422.112 are met for that individual through the M+C plan's established provider network. The M+C organization must furnish the same benefits to these enrollees as to enrollees who reside in the service area;

(4) Has been a member of an Employer Group Health Plan (EGHP) that includes the elected M+C plan, even if the individual lives outside of the M+C plan service area, provided that an M+C organization chooses to offer this option and that CMS determines that all applicable M+C access requirements at § 422.12 are met for that individual through the M+C plan's established provider network. The M+C organization must furnish the same benefits to

all enrollees, regardless of whether they reside in the service area;

(5) Completes and signs an election form and gives information required for enrollment; and

(6) Agrees to abide by the rules of the M+C organization after they are disclosed to him or her in connection with the election process.

(b) An M+C eligible individual may not be enrolled in more than one M+C plan at any given time.

[63 FR 35071, June 26, 1998; 63 FR 52611, Oct. 1, 1998, as amended at 65 FR 40316, June 29, 2000; 68 FR 50855, Aug. 22, 2003]

§ 422.54 Continuation of enrollment.

(a) *Definition. Continuation area* means an additional area (outside the service area) within which the M+C organization furnishes or arranges for furnishing services to its continuation-of-enrollment enrollees. Enrollees must reside in a continuation area on a permanent basis. A continuation area does not expand the service area of any plan.

(b) *Basic rule.* An M+C organization may offer a continuation of enrollment option to enrollees when they no longer reside in the service area of a plan and permanently move into the geographic area designated by the M+C organization as a continuation of enrollment area. The intent to no longer reside in an area and permanently live in another area is verified through documentation that establishes residency, such as, driver's license, voter registration.

(c) *General requirements.* (1) An M+C organization that wishes to offer a continuation of enrollment option must meet the following requirements:

(i) Obtain CMS's approval of the continuation area, the marketing materials that describe the option, and the M+C organization's assurances of access to services.

(ii) Describe the option(s) in the member materials it offers and make the option available to all enrollees residing in the continuation area.

(2) An enrollee who moves out of the service area into the geographic area designated as the continuation area has the choice of continuing enrollment or disenrolling from the plan. The enrollee must make the choice of continuing enrollment in a manner specified by CMS. If no choice is made, the enrollee must be disenrolled from the plan.

(d) *Specific requirements*—

(1) *Continuation of enrollment benefits.* The M+C organization must, at a minimum, provide or arrange for the Medicare-covered benefits as described in § 422.101(a).

(2) *Reasonable access.* The M+C organization must ensure reasonable access in the continuation area—

(i) Through contracts with providers, or through direct payment of claims that satisfy the requirements in § 422.100(b)(2), to other providers who meet the requirement in subpart E of this part; and

(ii) By ensuring that the access requirements of § 422.112 are met.

(3) *Reasonable cost-sharing.* For services furnished in the continuation area, an enrollee's cost-sharing liability is limited to the cost-sharing amounts required in the M+C plan's service area (in which the enrollee no longer resides).

(4) *Protection of enrollee rights.* An M+C organization that offers a continuation of enrollment option must convey all enrollee rights conferred under this rule, with the understanding that—

(i) The ultimate responsibility for all appeals and grievance requirements remain with the organization that is receiving payment from CMS; and

(ii) Organizations that require enrollees to give advance notice of intent to use the continuation of enrollment option, must stipulate the notification process in the marketing materials.

(e) *Capitation payments.* CMS's capitation payments to all M+C organizations, for all Medicare enrollees, are based on rates established on the basis of the enrollee's permanent residence, regardless of where he or she receives services.

[63 FR 35071, June 26, 1998; 63 FR 52611, Oct. 1, 1998, as amended at 65 FR 40316, June 29, 2000]

§ 422.56 Limitations on enrollment in an M+C MSA plan.

(a) *General.* An individual is not eligible to elect an M+C MSA plan—

(1) If the number of individuals enrolled in M+C MSA plans has reached 390,000;

(2) Unless the individual provides assurances that are satisfactory to CMS that he or she will reside in the United States for at least 183 days during the year for which the election is effective; or

(3) On or after January 1, 2003, unless the enrollment is the continuation of an enrollment in effect as of that date.

(b) *Individuals eligible for or covered under other health benefits program.* An individual who is enrolled in a Federal Employee Health Benefit plan under 5 U.S.C. chapter 89, or is eligible for health care benefits through the Veteran's Administration under 10 U.S.C. chapter 55 or the Department of Defense under 38 U.S.C. chapter 17, may not enroll in an M+C MSA plan.

(c) *Individuals eligible for Medicare cost-sharing under Medicaid State plans.* An individual who is entitled to coverage of Medicare cost-sharing under a State plan under title XIX of the Act is not eligible to enroll in an M+C MSA plan.

(d) *Other limitations.* An individual who receives health benefits that cover all or part of the annual deductible under the M+C MSA plan may not enroll in an M+C MSA plan. Examples of this type of coverage include, but are not limited to, primary health care coverage other than Medicare, current coverage under the Medicare hospice benefit, supplemental insurance policies not specifically permitted under §422.104, and retirement health benefits.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998]

§422.57 Limited enrollment under M+C RFB plans.

An RFB society that offers an M+C RFB plan may offer that plan only to members of the church, or convention or group of churches with which the society is affiliated.

§422.60 Election process.

(a) *Acceptance of enrollees: General rule.* (1) Except for the limitations on enrollment in an M+C MSA plan provided by §422.62(d)(1) and except as specified in paragraph (a)(2) of this section, each M+C organization must accept without restriction (except for an M+C RFB plan as provided by §422.57) individuals who are eligible to elect an M+C plan that the M+C organization offers and who elect an M+C plan during initial coverage election periods under §422.62(a)(1), annual election periods under §422.62(a)(2), and under the circumstances described in §422.62(b)(1) through (b)(4).

(2) M+C organizations must accept elections during the open enrollment periods specified in §422.62(a)(3), (a)(4), and (a)(5) if their M+C plans are open to new enrollees.

(b) *Capacity to accept new enrollees.* (1) M+C organizations may submit information on enrollment capacity of plans they offer by July 1 of each year as provided by §422.306(a)(1).

(2) If CMS determines that an M+C plan offered by an M+C organization has a capacity limit, and the number of M+C eligible individuals who elect to enroll in that plan exceeds the limit, the M+C organization offering the plan may limit enrollment in the plan under this part, but only if it provides priority in acceptance as follows:

(i) First, for individuals who elected the plan prior to the CMS determination that capacity has been exceeded, elections will be processed in chronological order by date of receipt of their election forms.

(ii) Then for other individuals in a manner that does not discriminate on the basis of any factor related to health as described in §422.110.

(3) CMS considers enrollment limit requests for an M+C plan service area, other than those submitted with the adjusted community rate proposal, or for a portion of the plan service area, only if the health and safety of beneficiaries is at risk, such as if the provider network is not available to serve the enrollees in all or a portion of the service area.

(c) *Election forms.* (1) The election form must comply with CMS instructions regarding content and format and have been approved by CMS as described in §422.80. The form must be completed and signed by the M+C eligible individual (or the individual who will soon become entitled to Medicare benefits) and include authorization for

disclosure and exchange of necessary information between the U.S. Department of Health and Human Services and its designees and the M+C organization. Persons who assist beneficiaries in completing forms must sign the form and indicate their relationship to the beneficiary.

(2) The M+C organization must file and retain election forms for the period specified in CMS instructions.

(d) *When an election is considered to have been made.* An election in an M+C plan is considered to have been made on the date the election form is received by the M+C organization.

(e) *Handling of election forms.* The M+C organization must have an effective system for receiving, controlling, and processing election forms. The system must meet the following conditions and requirements:

(1) Each election form is dated as of the day it is received.

(2) Election forms are processed in chronological order, by date of receipt.

(3) The M+C organization gives the beneficiary prompt written notice of acceptance or denial in a format specified by CMS.

(4) In a format specified by CMS, a notice of acceptance—

(i) Informs the beneficiary of the date on which enrollment will be effective under § 422.68; and

(ii) If the M+C plan is enrolled to capacity, explains the procedures that will be followed when vacancies occur.

(5) A notice of denial explains the reasons for denial in a format specified by CMS.

(6) Upon receipt of the election form or from the date a vacancy occurs for an individual who was accepted for future enrollment, the M+C organization transmits, within the timeframes specified by CMS, the information necessary for CMS to add the beneficiary to its records as an enrollee of the M+C organization.

(f) *Exception for employer group health plans.*

(1) In cases in which an M+C organization has both a Medicare contract and a contract with an employer group health plan, and in which the M+C organization arranges for the employer to process election forms for Medicare-entitled group members, who wish to enroll under the Medicare contract, the effective date of the election may be retroactive. Consistent with § 422.250(b), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

(2) In order to obtain the effective date described in paragraph (f)(1) of this section, the beneficiary must certify that, at the time of enrollment in the M+C organization, he or she received the disclosure statement specified in § 422.111.

(3) Upon receipt of the election form from the employer, the M+C organization must submit the enrollment within timeframes specified by CMS.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998; 63 FR 54526, Oct. 9, 1998; 64 FR 7980, Feb. 17, 1999; 65 FR 40316, June 29, 2000]

§ 422.62 Election of coverage under an M+C plan.

(a) *General: Coverage election periods—* (1) *Initial coverage election period.* The initial coverage election period is the period during which a new M+C eligible individual may make an initial election. This period begins 3 months prior to the month the individual is first entitled to both Part A and Part B and ends the last day of the month preceding the month of entitlement.

(2) *Annual election period.* (i) Beginning in 1999, the month of November is the annual election period for the following calendar year. Organizations offering M+C plans in January 1999 must open enrollment to Medicare beneficiaries in November 1998.

(ii) During the annual election period, an individual eligible to enroll in an M+C plan may change his or her election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan.

(3) *Open enrollment and disenrollment opportunities through 2001.* From 1998 through 2001, the number of elections or changes that an M+C eligible individual may make is not limited (except as provided for in paragraph (d) of this section for M+C MSA plans). Subject to the M+C plan being open to enrollees as provided under § 422.60(a)(2), an individual eligible to elect an M+C plan may change his or her election from an M+C plan to original Medicare or to a

different M+C plan, or from original Medicare to an M+C plan.

(4) *Open enrollment and disenrollment during 2002.* (i) Except as provided in paragraphs (a)(4)(ii), (a)(4)(iii), and (a)(6) of this section, an individual who is eligible to elect an M+C plan in 2002 may elect an M+C plan or change his or her election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan, but only once during the first 6 months of the year.

(ii) *Newly eligible M+C individual.* An individual who becomes an M+C eligible individual during 2002 may elect an M+C plan or original Medicare and then change his or her election once during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the 6th month of such entitlement, or on December 31, whichever is earlier. The individual can change the election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan during this period.

(iii) The limitation to one election or change in paragraphs (a)(4)(i) and (a)(4)(ii) of this section does not apply to elections or changes made during the annual election period specified in (a)(2) of this section or during a special enrollment period specified in paragraph (b) of this section.

(5) *Open enrollment and disenrollment beginning in 2003.* (i) For 2003 and subsequent years, except as provided in paragraphs (a)(5)(ii), (a)(5)(iii), and (a)(6) of this section, an individual who is eligible to elect an M+C plan may elect an M+C plan, change his or her election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan, but only once during the first 3 months of the year.

(ii) *Newly eligible M+C individual.* An individual who becomes an M+C eligible individual during 2003 or later may elect an M+C plan or original Medicare and then change his or her election once during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the 3rd month of such entitlement, or on December 31, whichever is earlier. The individual can change the election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan during this period.

(iii) The limitation to one election or change in paragraphs (a)(5)(i) and (a)(5)(ii) of this section does not apply to elections or changes made during the annual election period specified in paragraph (a)(2) of this section or during a special election period specified in paragraph (b) of this section.

(6) *Open enrollment period for institutionalized individuals.* After 2001, an individual who is eligible to elect an M+C plan and who is institutionalized, as defined by CMS, is not limited (except as provided for in paragraph (d) of this section for M+C MSA plans) in the number of elections or changes he or she may make. Subject to the M+C plan being open to enrollees as provided under § 422.60(a)(2), an M+C eligible institutionalized individual may at any time elect an M+C plan or change his or her election from an M+C plan to original Medicare, to a different M+C plan, or from iginal Medicare to an M+C plan.

(b) *Special election periods.* Effective as of January 1, 1999 for M+C MSA plans, and as of January 1, 2002, for all other types of M+C plans, an individual may at any time (that is, not limited to the annual election period) discontinue the election of an M+C plan offered by an M+C organization and change his or her election, in the form and manner specified by CMS, from an M+C plan to original Medicare or to a different M+C plan under any of the following circumstances:

(1) CMS or the organization has terminated the organization's contract for the plan, discontinued the plan in the area in which the individual resides, or the organization has notified the individual of the impending termination of the plan, or the impending discontinuation of the plan in the area in which the individual resides.

(2) The individual is not eligible to remain enrolled in the plan because of a change in his or her place of residence to a location out of the service area or continuation area or other change in circumstances as determined by CMS but not including terminations

resulting from a failure to make timely payment of an M+C monthly or supplemental beneficiary premium, or from disruptive behavior.

(3) The individual demonstrates to CMS, in accordance with guidelines issued by CMS, that—

(i) The organization offering the plan substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to the following:

(A) Failure to provide the beneficiary on a timely basis medically necessary services for which benefits are available under the plan.

(B) Failure to provide medical services in accordance with applicable quality standards; or

(ii) The organization (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in marketing the plan to the individual.

(4) The individual meets such other exceptional conditions as CMS may provide.

(c) *Special election period for individual age 65.* Effective January 1, 2002, an M+C eligible individual who elects an M+C plan during the initial enrollment period, as defined under section 1837(d) of the Act, that surrounds his or her 65th birthday (this period begins 3 months before and ends 3 months after the month of the individual's 65th birthday) may discontinue the election of that plan and elect coverage under original Medicare at any time during the 12-month period that begins on the effective date of enrollment in the M+C plan.

(d) *Special rules for M+C MSA plans*—(1) *Enrollment.* An individual may enroll in an M+C MSA plan only during an initial or annual election period described in paragraphs (a)(1) and (a)(2) of this section or during November 1998.

(2) *Disenrollment.* (i) Except as provided in paragraph (d)(2)(ii) of this section, an individual may disenroll from an M+C MSA plan only during—

(A) November 1998;

(B) An annual election period; or

(C) The special election period described in paragraph (b) of this section.

(ii) *Exception.* An individual who elects an M+C MSA plan during an annual election period and has never before elected an M+C MSA plan may revoke that election, no later than December 15 of that same year, by submitting to the organization that offers the M+C MSA plan a signed and dated request in the form and manner prescribed by CMS or by filing the appropriate disenrollment form through other mechanisms as determined by CMS.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 65 FR 40317, June 29, 2000]

§ 422.64 Information about the M+C program.

Each M+C organization must provide, on an annual basis, and in a format and using standard terminology that may be specified by CMS, the information necessary to enable CMS to provide to current and potential beneficiaries the information they need to make informed decisions with respect to the available choices for Medicare coverage.

[65 FR 40317, June 29, 2000]

§ 422.66 Coordination of enrollment and disenrollment through M+C organizations.

(a) *Enrollment.* An individual who wishes to elect an M+C plan offered by an M+C organization may make or change his or her election during the election periods specified in § 422.62 by filing the appropriate election form with the organization or through other mechanisms as determined by CMS.

(b) *Disenrollment*—(1) *Basic rule.* An individual who wishes to disenroll from an M+C plan may change his or her election during the election periods specified in § 422.62 in either of the following manners:

(i) Elect a different M+C plan by filing the appropriate election form with the M+C organization or through other mechanisms as determined by CMS.

(ii) Submit a signed and dated request for disenrollment to the M+C organization in the form and manner prescribed by CMS or file the appropriate disenrollment form through other mechanisms as determined by CMS.

(2) *When a disenrollment request is considered to have been made.* A disenrollment request is considered to have been made on the date the

disenrollment request is received by the M+C organization.

(3) *Responsibilities of the M+C organization.* The M+C organization must—

(i) Submit a disenrollment notice to CMS within timeframes specified by CMS;

(ii) Provide the enrollee with a copy of the request for disenrollment; and

(iii) In the case of a plan where lock-in applies, also provide the enrollee with a statement explaining that he or she—

(A) Remains enrolled until the effective date of disenrollment; and

(B) Until that date, neither the M+C organization nor CMS pays for services not provided or arranged for by the M+C plan in which the enrollee is enrolled; and

(iv) File and retain disenrollment requests for the period specified in CMS instructions.

(4) *Effect of failure to submit disenrollment notice to CMS promptly.* If the M+C organization fails to submit the correct and complete notice required in paragraph (b)(3)(i) of this section, the M+C organization must reimburse CMS for any capitation payments received after the month in which payment would have ceased if the requirement had been met timely.

(5) *Retroactive disenrollment.* CMS may grant retroactive disenrollment in the following cases:

(i) There never was a legally valid enrollment.

(ii) A valid request for disenrollment was properly made but not processed or acted upon.

(c) *Election by default: Initial coverage election period.* An individual who fails to make an election during the initial coverage election period is deemed to have elected original Medicare.

(d) *Conversion of enrollment (seamless continuation of coverage)*—(1) *Basic rule.* An M+C plan offered by an M+C organization must accept any individual (regardless of whether the individual has end-stage renal disease) who is enrolled in a health plan offered by the M+C organization during the month immediately preceding the month in which he or she is entitled to both Part A and Part B, and who meets the eligibility requirements at § 422.50.

(2) *Reserved vacancies.* Subject to CMS's approval, an M+C organization may set aside a reasonable number of vacancies in order to accommodate enrollment of conversions. Any set aside vacancies that are not filled within a reasonable time must be made available to other M+C eligible individuals.

(3) *Effective date of conversion.* If an individual chooses to remain enrolled with the M+C organization as an M+C enrollee, the individual's conversion to an M+C enrollee is effective the month in which he or she is entitled to both Part A and Part B in accordance with the requirements in paragraph (d)(5) of this section.

(4) *Prohibition against disenrollment.* The M+C organization may disenroll an individual who is converting under the provisions of paragraph (a) of this section only under the conditions specified in § 422.74.

(5) *Election form.* The individual who is converting must complete and sign an election form as described in § 422.60(c)(1).

(6) *Submittal of information to CMS.* The M+C organization must transmit the information necessary for CMS to add the individual to its records as specified in § 422.60(e)(6).

(e) *Maintenance of enrollment.* An individual who has made an election under this section is considered to have continued to have made that election until either of the following, which ever occurs first:

(1) The individual changes the election under this section.

(2) The elected M+C plan is discontinued or no longer serves the area in which the individual resides, the organization does not offer, or the individual does not elect, the option of continuing enrollment, as provided under either § 422.54 or § 422.74(b)(3)(ii).

(f) *Exception for employer group health plans.* (1) In cases when an M+C organization has both a Medicare contract and a contract with an employer group health plan, and in which the M+C organization arranges for the employer to process election forms for Medicare-entitled group members who wish to disenroll from the Medicare contract, the effective date of the election may be retroactive. Consistent with § 422.250(b), payment adjustments based

on a retroactive effective date may be made for up to a 90-day period.

(2) Upon receipt of the election form from the employer, the M+C organization must submit a disenrollment notice to CMS within timeframes specified by CMS.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 65 FR 40317, June 29, 2000]

§ 422.68 Effective dates of coverage and change of coverage.

(a) *Initial coverage election period.* An election made during an initial coverage election period as described in § 422.62(a)(1) is effective as of the first day of the month of entitlement to both Part A and Part B.

(b) *Annual election periods.* For an election or change of election made during an annual election period as described in § 422.62(a)(2), coverage is effective as of the first day of the following calendar year.

(c) *Open enrollment periods.* For an election, or change in election, made during an open enrollment period, as described in § 422.62(a)(3) through (a)(6), coverage is effective as of the first day of the first calendar month following the month in which the election is made.

(d) *Special election periods.* For an election or change of election made during a special election period as described in § 422.62(b), the effective date of coverage shall be determined by CMS, to the extent practicable, in a manner consistent with protecting the continuity of health benefits coverage.

(e) *Special election period for individual age 65.* For an election of coverage under original Medicare made during a special election period for an individual age 65 as described in § 422.62(c), coverage is effective as of the first day of the first calendar month following the month in which the election is made.

[63 FR 35071, June 26, 1998, as amended at 65 FR 40317, June 29, 2000; 67 FR 13288, Mar. 22, 2002]

§ 422.74 Disenrollment by the M+C organization.

(a) *General rule.* Except as provided in paragraphs (b) through (d) of this section, an M+C organization may not—

(1) Disenroll an individual from any M+C plan it offers; or

(2) Orally or in writing, or by any action or inaction, request or encourage an individual to disenroll.

(b) *Basis for disenrollment*—(1) *Optional disenrollment.* An M+C organization may disenroll an individual from an M+C plan it offers in any of the following circumstances:

(i) Any monthly basic and supplementary beneficiary premiums are not paid on a timely basis, subject to the grace period for late payment established under paragraph (d)(1) of this section.

(ii) The individual has engaged in disruptive behaviors specified at paragraph (d)(2) of this section.

(iii) The individual provides fraudulent information on his or her election form or permits abuse of his or her enrollment card as specified in paragraph (d)(3) of this section.

(2) *Required disenrollment.* An M+C organization must disenroll an individual from an M+C plan it offers in any of the following circumstances:

(i) The individual no longer resides in the M+C plan's service area as specified under paragraph (d)(4) of this section, is no longer eligible under § 422.50(a)(3)(ii), and optional continued enrollment has not been offered or elected under § 422.54.

(ii) The individual loses entitlement to Part A or Part B benefits as described in paragraph (d)(5) of this section.

(iii) Death of the individual as described in paragraph (d)(6) of this section.

(3) *Plan termination or reduction of area where plan is available.* (i) *General rule.* An M+C organization that has its contract for an M+C plan terminated, that terminates an M+C plan, or that discontinues offering the plan in any portion of the area where the plan had previously been available, must disenroll affected enrollees in accordance with the procedures for disenrollment set forth at paragraph (d)(7) of this section, unless the exception in paragraph (b)(3)(ii) of this section applies.

(ii) *Exception.* When an M+C organization discontinues offering an M+C plan in a portion of its service area, the

M+C organization may elect to offer enrollees residing in all or portions of the affected area the option to continue enrollment in an M+C plan offered by the organization, provided that there is no other M+C plan offered in the affected area at the time of the organization's election. The organization may require an enrollee who chooses to continue enrollment to agree to receive the full range of basic benefits (excluding emergency and urgently needed care) exclusively through facilities designated by the organization within the plan service area.

(c) *Notice requirement.* If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i), or (b)(3) of this section (that is, other than death or loss of entitlement to Part A or Part B) the M+C organization must give the individual a written notice of the disenrollment with an explanation of why the M+C organization is planning to disenroll the individual. Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) must—

(1) Be mailed to the individual before submission of the disenrollment notice to CMS; and

(2) Include an explanation of the individual's right to a hearing under the M+C organization's grievance procedures.

(d) *Process for disenrollment*—(1) *Monthly basic and supplementary premiums are not paid timely.* An M+C organization may disenroll an individual from the M+C plan for failure to pay any basic and supplementary premiums under the following circumstances:

(i) The M+C organization makes a reasonable effort to collect unpaid premium amounts by sending a written notice of nonpayment to the enrollee within 20 days after the date the delinquent charges were due—

(A) Alerting the individual that the premiums are delinquent;

(B) Providing the individual with an explanation of the disenrollment procedures and any lock-in requirements of the M+C plan; and

(C) Advising that failure to pay the premiums within the 90-day grace period will result in termination of M+C coverage;

(ii) The M+C organization has not received payment within 90 days after the date the premium was due.

(iii) The M+C organization gives the individual a written notice of disenrollment that meets the requirement set forth in paragraph (c) of this section.

(iv) If the enrollee fails to pay the premium for optional supplemental benefits (that is, a package of benefits that an enrollee is not required to accept), but pays the basic premium and any mandatory supplemental premium, the M+C organization has the option to discontinue the optional supplemental benefits and retain the individual as an M+C enrollee.

(2) *Disenrollment for disruptive behavior*—(i) *Basis for disenrollment.*An M+C organization may disenroll an individual from the M+C plan if the individual's behavior is disruptive, unruly, abusive, or uncooperative to the extent that his or her continued enrollment in the plan seriously impairs the M+C plan's ability to furnish services to either the particular individual or other individuals enrolled in the plan.

(ii) *Effort to resolve the problem.*The M+C organization must make a serious effort to resolve the problems presented by the individual, including the use (or attempted use) of the M+C organization's grievance procedures. The beneficiary has a right to submit any information or explanation that he or she may wish to submit to the M+C organization.

(iii) *Consideration of extenuating circumstances.* The M+C organization must establish that the individual's behavior is not related to the use of medical services or to diminished mental capacity.

(iv) *Documentation.* The M+C organization must document the enrollee's behavior, its own efforts to resolve any problems, and any extenuating circumstances, as described in paragraphs (d)(2)(i) through (d)(2)(iii) of this section.

(v) *CMS review of the M+C organization's proposed disenrollment.* (A) CMS decides after reviewing the documentation submitted by the M+C organization and any information submitted by the beneficiary (which the M+C organization must forward to CMS) whether

the M+C organization has met the disenrollment requirements.

(B) CMS makes the decision within 20 working days after receipt of the documentation and notifies the M+C organization within 5 working days after making its decision.

(vi) *Effective date of disenrollment.* If CMS permits an M+C organization to disenroll an individual for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the M+C organization gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(3) *Individual commits fraud or permits abuse of enrollment card.*—(i) *Basis for disenrollment.* An M+C organization may disenroll the individual from an M+C plan if the individual—

(A) Knowingly provides, on the election form, fraudulent information that materially affects the individual's eligibility to enroll in the M+C plan; or

(B) Intentionally permits others to use his or her enrollment card to obtain services under the M+C plan.

(ii) *Notice of disenrollment.* The M+C organization must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) *Report to CMS.* The M+C organization must report to CMS any disenrollment based on fraud or abuse by the individual.

(4) *Individual no longer resides in the M+C plan's service area*—(i) *Basis for disenrollment.* Unless continuation of enrollment is elected under §422.54, the M+C organization must disenroll an individual if the M+C organization establishes, on the basis of a written statement from the individual or other evidence acceptable to CMS, that the individual has permanently moved—

(A) Out of the M+C plan's service area; or

(B) From the residence in which the individual resided at the time of enrollment in the M+C plan to an area outside the M+C plan's service area, for those individuals who enrolled in the M+C plan under the eligibility requirements at §422.50(a)(3)(ii) or (a)(4).

(ii) *Special rule.* If the individual has not moved from the M+C plan's service area (or residence, as described in paragraph (d)(4)(i)(B) of this section), but has left the service area (or residence) for more than 6 months, the M+C organization must disenroll the individual from the plan, unless the exception in paragraph (d)(4)(iii) of this section applies.

(iii) *Exception.* If the M+C plan covers services other than emergent, urgent, maintenance and poststabilization, and renal dialysis services (as described in §422.100(b)(1)(iv) and §422.113) when the individual is out of the service area for a period of consecutive days longer than 6 months but less than 12 months, but within the United States (as defined in §400.200 of this chapter), the M+C organization may elect to offer to the individual the option of remaining enrolled in the M+C plan if—

(A) The individual is disenrolled on the first day of the 13th month after the individual left the service area (or residence, if paragraph (d)(4)(i)(B) of this section applies);

(B) The individual understands and accepts any restrictions imposed by the M+C plan on obtaining these services while absent from the M+C plan's service area for the extended period; and

(C) The M+C organization makes this option available to all Medicare enrollees who are absent for an extended period from the M+C plan's service area. However, M+C organizations may limit this option to enrollees who travel to certain areas, as defined by the M+C organization, and who receive services from qualified providers who directly provide, arrange for, or pay for health care.

(iv) *Notice of disenrollment.* The M+C organization must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(5) *Loss of entitlement to Part A or Part B benefits.* If an individual is no longer entitled to Part A or Part B benefits, CMS notifies the M+C organization that the disenrollment is effective the first day of the calendar month following the last month of entitlement to Part A or Part B benefits.

(6) *Death of the individual.* If the individual dies, disenrollment is effective

the first day of the calendar month following the month of death.

(7) *Plan termination or area reduction.* (i) When an M+C organization has its contract for an M+C plan terminated, terminates an M+C plan, or discontinues offering the plan in any portion of the area where the plan had previously been available, the M+C organization must give each affected M+C plan enrollee a written notice of the effective date of the plan termination or area reduction and a description of alternatives for obtaining benefits under the M+C program.

(ii) The notice must be sent before the effective date of the plan termination or area reduction, and in the timeframes specified in § 422.506(a)(2).

(e) *Consequences of disenrollment*—(1) *Disenrollment for non-payment of premiums, disruptive behavior, fraud or abuse, loss of Part A or Part B.* An individual who is disenrolled under paragraph (b)(1)(i), (b)(1)(ii), (b)(1)(iii), or paragraph (b)(2)(ii) of this section is deemed to have elected original Medicare.

(2) *Disenrollment based on plan termination, area reduction, or individual moves out of area.* (i) An individual who is disenrolled under paragraph (b)(2)(i) or (b)(3) of this section has a special election period in which to make a new election as provided in § 422.62(b)(1) and (b)(2).

(ii) An individual who fails to make an election during the special election period is deemed to have elected original Medicare.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 65 FR 40318, June 29, 2000; 68 FR 50855, Aug. 22, 2003]

§ 422.80 Approval of marketing materials and election forms.

(a) *CMS review of marketing materials.* An M+C organization may not distribute any marketing materials (as defined in paragraph (b)), or election forms, or make such materials or forms available to individuals eligible to elect an M+C plan, unless—

(1) At least 45 days (or 10 days if using marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution the M+C organization has submitted the material or form to CMS for review under the guidelines in paragraph (c); and

(2) CMS has not disapproved the distribution of the material or form.

(b) *Definition of marketing materials.* Marketing materials include any informational materials targeted to Medicare beneficiaries which:

(1) Promote the M+C organization, or any M+C plan offered by the M+C organization;

(2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in, an M+C plan offered by the M+C organization;

(3) Explain the benefits of enrollment in an M+C plan, or rules that apply to enrollees;

(4) Explain how Medicare services are covered under an M+C plan, including conditions that apply to such coverage;

(5) Examples of marketing materials include, but are not limited to:

(i) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the internet.

(ii) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(iii) Presentation materials such as slides and charts.

(iv) Promotional materials such as brochures or leaflets, including materials for circulation by third parties (*e.g.*, physicians or other providers).

(v) Membership communication materials such as membership rules, subscriber agreements (evidence of coverage), member handbooks and wallet card instructions to enrollees.

(vi) Letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures *etc.*

(vii) Membership or claims processing activities (*e.g.*, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or annual notification information).

(c) *Guidelines for CMS review.* In reviewing marketing material or election forms under paragraph (a) of this section, CMS determines that the marketing materials:

(1) Provide, in a format (and, where appropriate, print size), and using

standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling:

(i) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.

(ii) Adequate written description of any supplemental benefits and services.

(iii) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each.

(iv) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(2) Notify the general public of its enrollment period (whether time-limited or continuous) in an appropriate manner, through appropriate media, throughout its service and continuation area.

(3) Include in the written materials notice that the M+C organization is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the plan.

(4) Are not materially inaccurate or misleading or otherwise make material misreprepresentations.

(5) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

(d) *Deemed approval (one-stop shopping).* If CMS has not disapproved the distribution of marketing materials or forms submitted by an M+C organization with respect to an M+C plan in an area, CMS is deemed not to have disapproved the distribution in all other areas covered by the M+C plan and organization except with regard to any portion of the material or form that is specific to the particular area.

(e) *Standards for M+C organization marketing.* (1) In conducting marketing activities, M+C organizations may not:

(i) Provide for cash or other monetary rebates as an inducement for enrollment or otherwise. This does not prohibit explanation of any legitimate benefits the beneficiary might obtain as an enrollee of the M+C plan, such as eligibility to enroll in a supplemental benefit plan that covers deductibles and coinsurance, or preventive services.

(ii) Engage in any discriminatory activity such as, for example, attempts to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(iii) Solicit door-to-door for Medicare beneficiaries.

(iv) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the M+C organization. The M+C organization may not claim that it is recommended or endorsed by CMS or Medicare or that CMS or Medicare recommends that the beneficiary enroll in the M+C plan. It may, however, explain that the organization is approved for participation in Medicare.

(v) Distribute marketing materials for which, before expiration of the 45-day period, the M+C organization receives from CMS written notice of disapproval because it is inaccurate or misleading, or misrepresents the M+C organization, its marketing representatives, or CMS.

(vi) Use providers or provider groups to distribute printed information comparing the benefits of different health plans unless the materials have the concurrence of all M+C organizations involved and have received prior approval by CMS. Physicians or providers may distribute health plan brochures (exclusive of application forms) at a health fair or in their offices. Physicians may discuss, in response to an individual patient's inquiry, the various benefits in different health plans.

(vii) Accept plan applications in provider offices or other places where health care is delivered.

(viii) Employ M+C plan names that suggest that a plan is not available to all Medicare beneficiaries. This prohibition shall not apply to M+C plan names in effect on July 31, 2000.

(2) In its marketing, the M+C organization must:

(i) Demonstrate to CMS's satisfaction that marketing resources are allocated to marketing to the disabled

Medicare population as well as beneficiaries age 65 and over.

(ii) Establish and maintain a system for confirming that enrolled beneficiaries have in fact, enrolled in the M+C plan, and understand the rules applicable under the plan.

(f) *Employer group retiree marketing.* M+C organizations may develop marketing materials designed for members of an employer group who are eligible for employer-sponsored benefits through the M+C organization, and furnish these materials only to the group members. While the materials must be submitted for approval under paragraph (a) of this section, CMS will not review portions of these materials that relate to employer group benefits.

[63 FR 35071, June 26, 1998; 63 FR 52612, Oct. 1, 1998, as amended at 65 FR 40318, June 29, 2000; 67 FR 13288, Mar. 22, 2002]

Subpart C—Benefits and Beneficiary Protections

SOURCE: 63 FR 35077, June 26, 1998, unless otherwise noted.

§ 422.100 General requirements.

(a) *Basic rule.* Subject to the conditions and limitations set forth in this subpart, an M+C organization offering an M+C plan must provide enrollees in that plan with coverage of the basic benefits described in paragraph (c) of this section (and, to the extent applicable, the benefits described in §422.102) by furnishing the benefits directly or through arrangements, or by paying for the benefits. CMS reviews these benefits subject to the requirements of §422.100(g) and the requirements in subpart G of this part.

(b) *Services of noncontracting providers and suppliers.* (1) An M+C organization must make timely and reasonable payment to or on behalf of the plan enrollee for the following services obtained from a provider or supplier that does not contract with the M+C organization to provide services covered by the M+C plan:

(i) Ambulance services dispatched through 911 or its local equivalent as provided in §422.113.

(ii) Emergency and urgently needed services as provided in §422.113.

(iii) Maintenance and post-stabilization care services as provided in §422.113.

(iv) Renal dialysis services provided while the enrollee was temporarily outside the plan's service area.

(v) Services for which coverage has been denied by the M+C organization and found (upon appeal under subpart M of this part) to be services the enrollee was entitled to have furnished, or paid for, by the M+C organization.

(2) An M+C plan (other than an M+C MSA plan) offered by an M+C organization satisfies paragraph (a) of this section with respect to benefits for services furnished by a noncontracting provider if that M+C plan provides payment in an amount the provider would have received under original Medicare (including balance billing permitted under Medicare Part A and Part B).

(c) *Types of benefits.* An M+C plan includes at a minimum basic benefits, and also may include mandatory and optional supplemental benefits.

(1) Basic benefits are all Medicare-covered services, except hospice services, and additional benefits as defined in §422.2 and meeting all requirements in §422.312.

(2) Supplemental benefits, which consist of—

(i) Mandatory supplemental benefits are services not covered by Medicare that an M+C enrollee must purchase as part of an M+C plan that are paid for in full, directly by (or on behalf of) Medicare enrollees, in the form of premiums or cost-sharing.

(ii) Optional supplemental benefits are health services not covered by Medicare that are purchased at the option of the M+C enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost-sharing. These services may be grouped or offered individually.

(d) *Availability and structure of plans.* An M+C organization offering an M+C plan must offer it—

(1) To all Medicare beneficiaries residing in the service area of the M+C plan;

(2) At a uniform premium, with uniform benefits and level of cost-sharing throughout the plan's service area, or segment of service area as provided in §422.304(b)(2).

(e) *Terms of M+C plans.* Terms of M+C plans described in instructions to beneficiaries, as required by §422.111, will include basic and supplemental benefits and terms of coverage for those benefits.

(f) *Multiple plans in one service area.* An M+C organization may offer more than one M+C plan in the same service area subject to the conditions and limitations set forth in this subpart for each M+C plan.

(g) *CMS review and approval of M+C benefits.* CMS reviews and approves M+C benefits using written policy guidelines and requirements in this part, operational policy letters, and other CMS instructions to ensure that—

(1) Medicare-covered services meet CMS fee-for-service guidelines;

(2) M+C organizations are not designing benefits to discriminate against beneficiaries, promote discrimination, discourage enrollment, steer subsets of Medicare beneficiaries to particular M+C plans, or inhibit access to services; and

(3) Benefit design meets other M+C program requirements.

(h) *Benefits affecting screening mammography, influenza vaccine, and pneumoccal vaccine.* (1) Enrollees of M+C organizations may directly access (through self-referral) screening mammography and influenza vaccine.

(2) M+C organizations may not impose cost-sharing for influenza vaccine and pneumococcal vaccine on their M+C plan enrollees.

(i) *Requirements relating to Medicare conditions of participation.* Basic benefits must be furnished through providers meeting the requirements in §422.204(b)(3).

(j) *Provider networks.* The M+C plans offered by an M+C organization may share a provider network as long as each M+C plan independently meets the access and availability standards described at §422.112, as determined by CMS.

[65 FR 40319, June 29, 2000, as amended at 67 FR 13288, Mar. 22, 2002]

§422.101 Requirements relating to basic benefits.

Except as specified in §422.264 (for entitlement that begins or ends during a hospital stay) and §422.266 (with respect to hospice care), each M+C organization must meet the following requirements:

(a) Provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B) and that are available to beneficiaries residing in the plan's service area. Services may be provided outside of the service area of the plan if the services are accessible and available to enrollees.

(b) Comply with—

(1) CMS's national coverage determinations;

(2) General coverage guidelines included in original Medicare manuals and instructions unless superseded by operational policy letters or regulations in this part; and

(3) Written coverage decisions of local carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered under the M+C organization. If an M+C organization covers geographic areas encompassing more than one local coverage policy area, the M+C organization may elect to uniformly apply to plan enrollees in all areas the coverage policy that is the most beneficial to M+C enrollees. M+C organizations that elect this option must notify CMS before selecting the area that has local coverage policies that are most beneficial to M+C enrollees as follows:

(i) An M+C organization electing to adopt a uniform local coverage policy for a plan or plans must notify CMS at least 60 days before the date specified in §422.306(a), which is 60 days before the date adjusted community rate proposals are due for the subsequent year. Such notice must identify the plan or plans and service area or services areas to which the uniform local coverage policy or policies will apply, the competing local coverage policies involved, and a justification explaining why the selected local coverage policy or policies are most beneficial to M+C enrollees.

(ii) CMS will review notices provided under paragraph (b)(3)(i) of this section, evaluate the selected local coverage policy or policies based on such factors as cost, access, geographic distribution of enrollees, and health status of enrollees, and notify the M+C organization of its approval or denial of the selected uniform local coverage policy or policies.

(c) M+C organizations may elect to furnish, as part of their Medicare covered benefits, coverage of posthospital SNF care as described in subparts C and D of this part, in the absence of the prior qualifying hospital stay that would otherwise be required for coverage of this care.

[65 FR 40319, June 29, 2000, as amended at 68 FR 50856, Aug. 22, 2003]

§ 422.102 Supplemental benefits.

(a) *Mandatory supplemental benefits.* (1) Subject to CMS's approval, an M+C organization may require Medicare enrollees of an M+C plan other than an MSA plan to accept and pay for services in addition to Medicare-covered services described in §422.101 and additional benefits described in §422.312.

(2) If the M+C organization imposes mandatory supplemental benefits, it must impose them on all Medicare beneficiaries enrolled in the M+C plan.

(3) CMS approves mandatory supplemental benefits if the benefits are designed in accordance with CMS's guidelines and requirements as stated in this part and instructions and operational policy letters.

(b) *Optional supplemental benefits.* Except as provided in §422.104 in the case of MSA plans, each M+C organization may offer (for election by the enrollee and without regard to health status) services that are not included in the basic benefits as described in §422.100(c) and any mandatory supplemental benefits described in paragraph (a) of this section. Optional supplemental benefits are purchased at the discretion of the enrollee and must be offered to all Medicare beneficiaries enrolled in the M+C plan.

(c) *Payment for supplemental services.* All supplemental benefits are paid for in full, directly by (or on behalf of) the enrollee of the M+C plan.

(d) *Marketing of supplemental benefits.* M+C organizations may offer enrollees a group of services as one optional supplemental benefit, offer services individually, or offer a combination of groups and individual services.

[65 FR 40320, June 29, 2000]

§ 422.103 Benefits under an M+C MSA plan.

(a) *General rule.* An M+C organization offering an M+C MSA plan must make available to an enrollee, or provide reimbursement for, at least the services described under in §422.101 after the enrollee incurs countable expenses equal to the amount of the plan's annual deductible.

(b) *Countable expenses.* An M+C organization offering an M+C MSA plan must count toward the annual deductible at least all amounts that would be paid for the particular service under original Medicare, including amounts that would be paid by the enrollee as deductibles or coinsurance.

(c) *Services after the deductible.* For services received by the enrollee after the annual deductible is satisfied, an M+C organization offering an M+C MSA plan must pay, at a minimum, the lesser of the following amounts:

(1) 100 percent of the expense of the services.

(2) 100 percent of the amounts that would have been paid for the services under original Medicare, including amounts that would be paid by the enrollee as deductibles and coinsurance.

(d) *Annual deductible.* The annual deductible for an M+C MSA plan—

(1) For contract year 1999, may not exceed $6,000; and

(2) For subsequent contract years may not exceed the deductible for the preceding contract year, increased by the national per capita growth percentage determined under §422.252(b).

§ 422.104 Special rules on supplemental benefits for M+C MSA plans.

(a) An M+C organization offering an M+C MSA plan may not provide supplemental benefits that cover expenses that count towards the deductible specified in §422.103(d).

(b) In applying the limitation of paragraph (a) of this section, the following kinds of policies are not considered as covering the deductible:

(1) A policy that provides coverage (whether through insurance or otherwise) for accidents, disability, dental care, vision care, or long-term care.

(2) A policy of insurance in which substantially all of the coverage relates to liabilities incurred under workers' compensation laws, tort liabilities, liabilities relating to use or ownership of property, and any other similar liabilities that CMS may specify by regulation.

(3) A policy of insurance that provides coverage for a specified disease or illness or pays a fixed amount per day (or other period) of hospitalization.

§ 422.105 Special rules for point of service option.

(a) *General rule.* A POS benefit is an option that an M+C organization may offer in an M+C coordinated care plan or network M+C MSA plan to provide enrollees with additional choice in obtaining specified health care services. The organization may offer a POS option—

(1) Under a coordinated care plan only as an additional benefit as described in § 422.312;

(2) Under a coordinated care plan only as a mandatory supplemental benefit as described in § 422.102(a); or

(3) Under a coordinated care plan or network MSA plan as an optional supplemental benefit as described in § 422.102(b).

(b) *Approval required.* An M+C organization may not implement a POS benefit until it has been approved by CMS.

(c) *Ensuring availability and continuity of care.* An M+C network plan that includes a POS benefit must continue to provide all benefits and ensure access as required under this subpart.

(d) *Enrollee information and disclosure.* The disclosure requirements specified in § 422.111 apply in addition to the following requirements:

(1) *Written rules.* M+C organizations must maintain written rules on how to obtain health benefits through the POS benefit.

(2) *Evidence of coverage document.* The M+C organization must provide to beneficiaries enrolling in a plan with a POS benefit an "evidence of coverage" document, or otherwise provide written documentation, that specifies all costs and possible financial risks to the enrollee, including—

(i) Any premiums and cost-sharing for which the enrollee is responsible;

(ii) Annual limits on benefits and on out-of-pocket expenditures;

(iii) Potential financial responsibility for services for which the plan denies payment because they were not covered under the POS benefit, or exceeded the dollar limit for the benefit; and

(iv) The annual maximum out-of-pocket expense an enrollee could incur.

(e) *Prompt payment.* Health benefits payable under the POS benefit are subject to the prompt payment requirements in § 422.520.

(f) *POS-related data.* An M+C organization that offers a POS benefit through an M+C plan must report enrollee utilization data at the plan level by both plan contracting providers (in-network) and by non-contracting providers (out-of-network) including enrollee use of the POS benefit, in the form and manner prescribed by CMS.

[63 FR 35077, June 26, 1998, as amended at 65 FR 40320, June 29, 2000]

§ 422.106 Coordination of benefits with employer or union group health plans and Medicaid.

(a) *General rule.* If an M+C organization contracts with an employer, labor organization, or the trustees of a fund established by one or more employers or labor organizations that cover enrollees in an M+C plan, or contracts with a State Medicaid agency to provide Medicaid benefits to individuals who are eligible for both Medicare and Medicaid, and who are enrolled in an M+C plan, the enrollees must be provided the same benefits as all other enrollees in the M+C plan, with the employer, labor organization, fund trustees, or Medicaid benefits supplementing the M+C plan benefits. Jurisdiction regulating benefits under these circumstances is as follows:

(1) All requirements of this part that apply to the M+C program apply to the M+C plan coverage and benefits provided to enrollees eligible for benefits

under an employer, labor organization, trustees of a fund established by one or more employers or labor organizations, or Medicaid contract.

(2) Employer benefits that complement an M+C plan, which are not part of the M+C plan, are not subject to review or approval by CMS.

(3) Medicaid benefits are not reviewed under this part, but are subject to appropriate CMS review under the Medicaid program. M+C plan benefits provided to individuals entitled to Medicaid benefits provided by the M+C organization under a contract with the State Medicaid agency are subject to M+C rules and requirements.

(b) *Examples.* Permissible employer, labor organization, benefit fund trustee, or Medicaid plan benefits include the following:

(1) Payment of a portion or all of the M+C basic and supplemental premiums.

(2) Payment of a portion or all of other cost-sharing amounts approved for the M+C plan.

(3) Other employer-sponsored benefits that may require additional premium and cost-sharing, or other benefits provided by the organization under a contract with the State Medicaid agency.

(c) *Waiver or modification.* (1) M+C organizations may request, in writing, from CMS, a waiver or modification of those requirements in this part that hinder the design of, the offering of, or the enrollment in, M+C plans under contracts between M+C organizations and employers, labor organizations, or the trustees of funds established by one or more employers or labor organizations to furnish benefits to the entity's employees, former employees, or members or former members of the labor organizations.

(2) Approved waivers or modifications under this paragraph may be used by any M+C organization in developing its Adjusted Community Rate (ACR) proposal. Any M+C organization using a waiver or modification must include that information in the cover letter of its ACR proposal submission.

[65 FR 40320, June 29, 2000, as amended at 68 FR 50856, Aug. 22, 2003]

§ 422.108 Medicare secondary payer (MSP) procedures.

(a) *Basic rule.* CMS does not pay for services to the extent that Medicare is not the primary payer under section 1862(b) of the Act and part 411 of this chapter.

(b) *Responsibilities of the M+C organization.* The M+C organization must, for each M+C plan—

(1) Identify payers that are primary to Medicare under section 1862(b) of the Act and part 411 of this chapter;

(2) Identify the amounts payable by those payers; and

(3) Coordinate its benefits to Medicare enrollees with the benefits of the primary payers.

(c) *Collecting from other entities.* The M+C organization may bill, or authorize a provider to bill, other individuals or entities for covered Medicare services for which Medicare is not the primary payer, as specified in paragraphs (d) and (e) of this section.

(d) *Collecting from other insurers or the enrollee.* If a Medicare enrollee receives from an M+C organization covered services that are also covered under State or Federal workers' compensation, any no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the M+C organization may bill, or authorize a provider to bill any of the following—

(1) The insurance carrier, the employer, or any other entity that is liable for payment for the services under section 1862(b) of the Act and part 411 of this chapter.

(2) The Medicare enrollee, to the extent that he or she has been paid by the carrier, employer, or entity for covered medical expenses.

(e) *Collecting from group health plans (GHPs) and large group health plans (LGHPs).* An M+C organization may bill a GHP or LGHP for services it furnishes to a Medicare enrollee who is also covered under the GHP or LGHP and may bill the Medicare enrollee to the extent that he or she has been paid by the GHP or LGHP.

(f) *MSP rules and State laws.* Consistent with §422.402 concerning the Federal preemption of State law, the rules established under this section supersede any State laws, regulations,

contract requirements, or other standards that would otherwise apply to M+C plans only to the extent that those State laws are inconsistent with the standards established under this part. A State cannot take away an M+C organization's right under Federal law and the MSP regulations to bill, or to authorize providers and suppliers to bill, for services for which Medicare is not the primary payer. Section 1852(a)(4) of the Social Security Act does not prohibit a State from limiting the amount of the recovery; thus, State law could modify, but not negate, an M+C organization's rights in this regard.

[63 FR 35077, June 26, 1998, as amended at 65 FR 40320, June 29, 2000]

§422.109 Effect of national coverage determinations (NCDs) and legislative changes in benefits.

(a) *Definitions.* The term *significant cost,* as it relates to a particular NCD or legislative change in benefits, means either of the following:

(1) The average cost of furnishing a single service exceeds a cost threshold that—

(i) For calendar years 1998 and 1999, is $100,000; and

(ii) For calendar year 2000 and subsequent calendar years, is the preceding year's dollar threshold adjusted to reflect the national per capita growth percentage described in §422.254(b).

(2) The estimated cost of all Medicare services furnished as a result of a particular NCD or legislative change in benefits represents at least 0.1 percent of the national standardized annual capitation rate, as described in §422.254(f), multiplied by the total number of Medicare beneficiaries for the applicable calendar year. For purposes of §422.256 only, this test is applied to all NCDs or legislative changes in benefits, in the aggregate, for a given year. If the sum of the average cost of each NCD or legislative change in benefits exceeds the amount in paragraph (a)(1) of this section, or the aggregate costs of all NCDs and legislative changes for a year exceeds the percentage in paragraph (a)(2) of this section, the costs are considered "significant."

(b) *General rule.* If CMS determines and announces that an individual NCD or legislative change in benefits meets the criteria for significant cost described in paragraph (a) of this section, a M+C organization is not required to assume risk for the costs of that service or benefit until the contract year for which payments are appropriately adjusted to take into account the cost of the NCD service or legislative change in benefits. If CMS determines that an NCD or legislative change in benefits does not meet the "significant cost" threshold described in §422.109(a), the M+C organization is required to provide coverage for the NCD or legislative change in benefits and assume risk for the costs of that service or benefit as of the effective date stated in the NCD or specified in the legislation.

(c) *Before payment adjustments become effective.* Before the contract year that payment adjustments that take into account the significant cost of the NCD service or legislative change in benefits become effective, the service or benefit is not included in the M+C organization's contract with CMS, and is not a covered benefit under the contract. The following rules apply to these services or benefits:

(1) Medicare payment for the service or benefit is made directly by the fiscal intermediary and carrier to the provider furnishing the service or benefit in accordance with original Medicare payment rules, methods, and requirements.

(2) Costs for NCD services or legislative changes in benefits for which CMS intermediaries and carriers will not make payment and are the responsibility of the M+C organization are—

(i) Services necessary to diagnose a condition covered by the NCD or legislative changes in benefits;

(ii) Most services furnished as follow-up care to the NCD service or legislative change in benefits;

(iii) Any service that is already a Medicare-covered service and included in the annual M+C capitation rate or previously adjusted payments; and

(iv) Any service, including the costs of the NCD service or legislative change in benefits, to the extent the M+C organization is already obligated

to cover it as an additional benefit under § 422.312 or supplemental benefit under § 422.102.

(3) Costs for significant cost NCD services or legislative changes in benefits for which CMS fiscal intermediaries and carriers will make payment are—

(i) Costs relating directly to the provision of services related to the NCD or legislative change in benefits that were noncovered services before the issuance of the NCD or legislative change in benefits; and

(ii) A service that is not included in the M+C capitation payment rate.

(4) Beneficiaries are liable for any applicable coinsurance amounts.

(d) *After payment adjustments become effective.* For the contract year in which payment adjustments that take into account the significant cost of the NCD service or legislative change in benefits are in effect, the service or benefit is included in the M+C organization's contract with CMS, and is a covered benefit under the contract. Subject to all applicable rules under this part, the M+C organization must furnish, arrange, or pay for the NCD service or legislative change in benefits. M+C organizations may establish separate plan rules for these services and benefits, subject to CMS review and approval. CMS may, at its discretion, issue overriding instructions limiting or revising the M+C plan rules, depending on the specific NCD or legislative change in benefits. For these services or benefits, the Medicare enrollee will be responsible for M+C plan cost sharing, as approved by CMS or unless otherwise instructed by CMS.

[68 FR 50856, Aug. 22, 2003]

§ 422.110 Discrimination against beneficiaries prohibited.

(a) *General prohibition.* Except as provided in paragraph (b) of this section, an M+C organization may not deny, limit, or condition the coverage or furnishing of benefits to individuals eligible to enroll in an M+C plan offered by the organization on the basis of any factor that is related to health status, including, but not limited to the following:

(1) Medical condition, including mental as well as physical illness.

(2) Claims experience.

(3) Receipt of health care.

(4) Medical history.

(5) Genetic information.

(6) Evidence of insurability, including conditions arising out of acts of domestic violence.

(7) Disability.

(b) *Exception.* An M+C organization may not enroll an individual who has been medically determined to have end-stage renal disease. However, an enrollee who develops end-stage renal disease while enrolled in a particular M+C organization may not be disenrolled for that reason. An individual who is an enrollee of a particular M+C organization, and resides in the M+C plan service area at the time he or she first becomes M+C eligible, is considered to be "enrolled" in the M+C organization for purposes of the preceding sentence.

(c) *Additional requirements.* An M+C organization is required to observe the provisions of the Civil Rights Act, Age Discrimination Act, Rehabilitation Act of 1973, and Americans with Disabilities Act (see § 422.502(h)).

[63 FR 35077, June 26, 1998; 63 FR 52612, Oct. 1, 1998; 64 FR 7980, Feb. 17, 1999, as amended at 65 FR 40321, June 29, 2000]

§ 422.111 Disclosure requirements.

(a) *Detailed description.* An M+C organization must disclose the information specified in paragraph (b) of this section—

(1) To each enrollee electing an M+C plan it offers;

(2) In clear, accurate, and standardized form; and

(3) At the time of enrollment and at least annually thereafter.

(b) *Content of plan description.* The description must include the following information:

(1) *Service area.* The M+C plan's service area and any enrollment continuation area.

(2) *Benefits.* The benefits offered under the plan, including applicable conditions and limitations, premiums and cost-sharing (such as copayments, deductibles, and coinsurance) and any other conditions associated with receipt or use of benefits; and for purposes of comparison—

(i) The benefits offered under original Medicare, including the content specified in paragraph (f)(1) of this section;

(ii) For an M+C MSA plan, the benefits under other types of M+C plans; and

(iii) The availability of the Medicare hospice option and any approved hospices in the service area, including those the M+C organization owns, controls, or has a financial interest in.

(3) *Access.* The number, mix, and distribution (addresses) of providers from whom enrollees may obtain services; any out-of network coverage; any point-of-service option, including the supplemental premium for that option; and how the M+C organization meets the requirements of §§422.112 and 422.114 for access to services offered under the plan.

(4) Out-of-area coverage provided under the plan, including coverage provided to individuals eligible to enroll in the plan under §422.50(a)(3)(ii).

(5) *Emergency coverage.* Coverage of emergency services, including—

(i) Explanation of what constitutes an emergency, referencing the definitions of emergency services and emergency medical condition at §422.113;

(ii) The appropriate use of emergency services, stating that prior authorization cannot be required;

(iii) The process and procedures for obtaining emergency services, including use of the 911 telephone system or its local equivalent; and

(iv) The locations where emergency care can be obtained and other locations at which contracting physicians and hospitals provide emergency services and post-stabilization care included in the M+C plan.

(6) *Supplemental benefits.* Any mandatory or optional supplemental benefits and the premium for those benefits.

(7) *Prior authorization and review rules.* Prior authorization rules and other review requirements that must be met in order to ensure payment for the services. The M+C organization must instruct enrollees that, in cases where noncontracting providers submit a bill directly to the enrollee, the enrollee should not pay the bill, but submit it to the M+C organization for processing and determination of enrollee liability, if any.

(8) *Grievance and appeals procedures.* All grievance and appeals rights and procedures.

(9) *Quality assurance program.* A description of the quality assurance program required under §422.152.

(10) *Disenrollment rights and responsibilities.*

(c) *Disclosure upon request.* Upon request of an individual eligible to elect an M+C plan, an M+C organization must provide to the individual the following information:

(1) The information required paragraph (f) of this section.

(2) The procedures the organization uses to control utilization of services and expenditures.

(3) The number of disputes, and the disposition in the aggregate, in a manner and form described by the Secretary. Such disputes shall be categorized as

(i) Grievances according to §422.564; and

(ii) Appeals according to §422.578 et. seq.

(4) A summary description of the method of compensation for physicians.

(5) Financial condition of the M+C organization, including the most recently audited information regarding, at least, a description of the financial condition of the M+C organization offering the plan.

(d) *Changes in rules.* If an M+C organization intends to change its rules for an M+C plan, it must:

(1) Submit the changes for CMS review under the procedures of §422.80.

(2) For changes that take effect on January 1, notify all enrollees by the previous October 15.

(3) For all other changes, notify all enrollees at least 30 days before the intended effective date of the changes.

(e) *Changes to provider network.* The M+C organization must make a good faith effort to provide written notice of a termination of a contracted provider at least 30 calendar days before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contracted is terminating, irrespective of whether

the termination was for cause or without cause. When a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must be notified.

(f) *Disclosable information*—(1) *Benefits under original Medicare.* (i) Covered services.

(ii) Beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts.

(iii) Any beneficiary liability for balance billing.

(2) *Enrollment procedures.* Information and instructions on how to exercise election options under this subpart.

(3) *Rights.* A general description of procedural rights (including grievance and appeals procedures) under original Medicare and the M+C program and the right to be protected against discrimination based on factors related to health status in accordance with § 422.110.

(4) *Medigap and Medicare Select.* A general description of the benefits, enrollment rights, and requirements applicable to Medicare supplemental policies under section 1882 of the Act, and provisions relating to Medicare Select policies under section 1882(t) of the Act.

(5) *Potential for contract termination.* The fact that an M+C organization may terminate or refuse to renew its contract, or reduce the service area included in its contract, and the effect that any of those actions may have on individuals enrolled in that organization's M+C plan.

(6) *Comparative information.* A list of M+C plans that are or will be available to residents of the service area in the following calendar year, and, for each available plan, information on the aspects described in paragraphs (c)(7) through (c)(11) of this section, presented in a manner that facilitates comparison among the plans.

(7) *Benefits.* (i) Covered services beyond those provided under original Medicare.

(ii) Any beneficiary cost-sharing.

(iii) Any maximum limitations on out-of-pocket expenses.

(iv) In the case of an M+C MSA plan, the amount of the annual MSA deposit and the differences in cost-sharing, enrollee premiums, and balance billing, as compared to M+C plans.

(v) In the case of an M+C private fee-for-service plan, differences in cost-sharing, enrollee premiums, and balance billing, as compared to M+C plans.

(vi) The extent to which an enrollee may obtain benefits through out-of-network health care providers.

(vii) The types of providers that participate in the plan's network and the extent to which an enrollee may select among those providers.

(viii) The coverage of emergency and urgently needed services.

(8) *Premiums.* (i) The M+C monthly basic beneficiary premiums.

(ii) The M+C monthly supplemental beneficiary premium.

(iii) The reduction in Part B premiums, if any.

(9) *The plan's service area.*

(10) *Quality and performance indicators* for benefits under a plan to the extent they are available as follows (and how they compare with indicators under original Medicare):

(i) Disenrollment rates for Medicare enrollees for the 2 previous years, excluding disenrollment due to death or moving outside the plan's service area, calculated according to CMS guidelines.

(ii) Medicare enrollee satisfaction.

(iii) Health outcomes.

(iv) Plan-level appeal data.

(v) The recent record of plan compliance with the requirements of this part, as determined by the Secretary.

(vi) Other performance indicators.

(11) *Supplemental benefits.* Whether the plan offers mandatory supplemental benefits or offers optional supplemental benefits and the premiums and other terms and conditions for those benefits.

[63 FR 35077, June 26, 1998, as amended at 64 FR 7980, Feb. 17, 1999; 65 FR 40321, June 29, 2000; 68 FR 50857, Aug. 22, 2003]

§ 422.112 Access to services.

(a) *Rules for coordinated care plans and network M+C MSA plans.* An M+C organization that offers an M+C coordinated care plan or network M+C MSA plan may specify the networks of providers from whom enrollees may obtain

services if the M+C organization ensures that all covered services, including additional or supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan. To accomplish this, the M+C organization must meet the following requirements:

(1) *Provider network.* Maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. These providers are typically utilized in the network as primary care providers (PCPs), specialists, hospitals, skilled nursing facilities, home health agencies, ambulatory clinics, and other providers.

(2) *PCP panel.* Establish a panel of PCPs from which the enrollee may select a PCP. If an M+C organization requires its enrollees to obtain a referral in most situations before receiving services from a specialist, the M+C organization must either assign a PCP for purposes of making the needed referral or make other arrangements to ensure access to medically necessary specialty care.

(3) *Specialty care.* Provide or arrange for necessary specialty care, and in particular give women enrollees the option of direct access to a women's health specialist within the network for women's routine and preventive health care services provided as basic benefits (as defined in §422.2). The M+C organization arranges for specialty care outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs.

(4) *Serious medical conditions.* Ensure that for each plan, the M+C organization has in effect CMS-approved procedures that enable the M+C organization, through appropriate health care professionals, to—

(i) Identify individuals with complex or serious medical conditions;

(ii) Assess those conditions, and use medical procedures to diagnose and monitor them on an ongoing basis; and

(iii) Establish and implement a treatment plan that—

(A) Is appropriate to those conditions;

(B) Includes an adequate number of direct access visits to specialists consistent with the treatment plan;

(C) Is time-specific and updated periodically; and

(D) Ensures adequate coordination of care among providers.

(5) *Service area expansion.* If seeking a service area expansion for an M+C plan, demonstrate that the number and type of providers available to plan enrollees are sufficient to meet projected needs of the population to be served.

(6) *Credentialed providers.* Demonstrate to CMS that its providers in an M+C plan are credentialed through the process set forth at §422.204(a).

(7) *Written standards.* Establish written standards for the following:

(i) Timeliness of access to care and member services that meet or exceed standards established by CMS. Timely access to care and member services within a plan's provider network must be continuously monitored to ensure compliance with these standards, and the M+C organization must take corrective action as necessary.

(ii) Policies and procedures (coverage rules, practice guidelines, payment policies, and utilization management) that allow for individual medical necessity determinations.

(iii) Provider consideration of beneficiary input into the provider's proposed treatment plan.

(8) *Hours of operation.* Ensure that—

(i) The hours of operation of its M+C plan providers are convenient to the population served under the plan and do not discriminate against Medicare enrollees; and

(ii) Plan services are available 24 hours a day, 7 days a week, when medically necessary.

(9) *Cultural considerations.* Ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds.

(10) *Ambulance services, emergency and urgently needed services, and post-stabilization care services coverage.* Provide coverage for ambulance services, emergency and urgently needed services, and post-stabilization care services in accordance with §422.113.

(b) *Rules for all M+C organizations to ensure continuity of care.* The M+C organization must ensure continuity of care and integration of services through arrangements that include, but are not limited to the following—

(1) Policies that specify under what circumstances services are coordinated and the methods for coordination;

(2) Offering to provide each enrollee with an ongoing source of primary care and providing a primary care source to each enrollee who accepts the offer;

(3) Programs for coordination of plan services with community and social services generally available through contracting or noncontracting providers in the area served by the M+C plan, including nursing home and community-based services; and

(4) Procedures to ensure that the M+C organization and its provider network have the information required for effective and continuous patient care and quality review, including procedures to ensure that—

(i) The M+C organization makes a "best-effort" attempt to conduct an initial assessment of each enrollee's health care needs, including following up on unsuccessful attempts to contact an enrollee, within 90 days of the effective date of enrollment;

(ii) Each provider, supplier, and practitioner furnishing services to enrollees maintains an enrollee health record in accordance with standards established by the M+C organization, taking into account professional standards; and

(iii) There is appropriate and confidential exchange of information among provider network components.

(5) Procedures to ensure that enrollees are informed of specific health care needs that require follow-up and receive, as appropriate, training in self-care and other measures they may take to promote their own health; and

(6) Systems to address barriers to enrollee compliance with prescribed treatments or regimens.

[64 FR 7980, Feb. 17, 1999, as amended at 65 FR 40321, June 29, 2000]

§ 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

(a) *Ambulance services.* The M+C organization is financially responsible for ambulance services, including ambulance services dispatched through 911 or its local equivalent, where other means of transportation would endanger the beneficiary's health.

(b) *Emergency and urgently needed services.*— (1) *Definitions.*

(i) *Emergency medical condition* means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

(A) Serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of the woman or her unborn child;

(B) Serious impairment to bodily functions; or

(C) Serious dysfunction of any bodily organ or part.

(ii) *Emergency services* means covered inpatient and outpatient services that are—

(A) Furnished by a provider qualified to furnish emergency services; and

(B) Needed to evaluate or stabilize an emergency medical condition.

(iii) *Urgently needed services* means covered services that are not emergency services as defined this section, provided when an enrollee is temporarily absent from the M+C plan's service (or, if applicable, continuation) area (or, under unusual and extraordinary circumstances, provided when the enrollee is in the service or continuation area but the organization's provider network is temporarily unavailable or inaccessible) when the services are medically necessary and immediately required—

(A) As a result of an unforeseen illness, injury, or condition; and

(B) It was not reasonable given the circumstances to obtain the services through the organization offering the M+C plan.

(2) *M+C organization financial responsibility*. The M+C organization is financially responsible for emergency and urgently needed services—

(i) Regardless of whether the services are obtained within or outside the M+C organization;

(ii) Regardless of whether there is prior authorization for the services.

(A) Instructions to seek prior authorization for emergency or urgently needed services may not be included in any materials furnished to enrollees (including wallet card instructions), and enrollees must be informed of their right to call 911.

(B) Instruction to seek prior authorization before the enrollee has been stabilized may not be included in any materials furnished to providers (including contracts with providers);

(iii) In accordance with the prudent layperson definition of *emergency medical condition* regardless of final diagnosis;

(iv) For which a plan provider or other M+C organization representative instructs an enrollee to seek emergency services within or outside the plan; and

(v) With a limit on charges to enrollees for emergency services of $50 or what it would charge the enrollee if he or she obtained the services through the M+C organization, whichever is less.

(3) *Stabilized condition*. The physician treating the enrollee must decide when the enrollee may be considered stabilized for transfer or discharge, and that decision is binding on the M+C organization.

(c) *Maintenance care and post-stabilization care services* (hereafter together referred to as "post-stabilization care services").

(1) *Definition*. *Post-stabilization care services* means covered services, related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or, under the circumstances described in paragraph (c)(2)(iii) of this section, to improve or resolve the enrollee's condition.

(2) *M+C organization financial responsibility*. The M+C organization—

(i) Is financially responsible (consistent with §422.214) for post-stabilization care services obtained within or outside the M+C organization that are pre-approved by a plan provider or other M+C organization representative;

(ii) Is financially responsible for post-stabilization care services obtained within or outside the M+C organization that are not pre-approved by a plan provider or other M+C organization representative, but administered to maintain the enrollee's stabilized condition within 1 hour of a request to the M+C organization for pre-approval of further post-stabilization care services;

(iii) Is financially responsible for post-stabilization care services obtained within or outside the M+C organization that are not pre-approved by a plan provider or other M+C organization representative, but administered to maintain, improve, or resolve the enrollee's stabilized condition if—

(A) The M+C organization does not respond to a request for pre-approval within 1 hour;

(B) The M+C organization cannot be contacted; or

(C) The M+C organization representative and the treating physician cannot reach an agreement concerning the enrollee's care and a plan physician is not available for consultation. In this situation, the M+C organization must give the treating physician the opportunity to consult with a plan physician and the treating physician may continue with care of the patient until a plan physician is reached or one of the criteria in §422.113(c)(3) is met; and

(iv) Must limit charges to enrollees for post-stabilization care services to an amount no greater than what the organization would charge the enrollee if he or she had obtained the services through the M+C organization.

(3) *End of M+C organization's financial responsibility*. The M+C organization's financial responsibility for post-stabilization care services it has not pre-approved ends when—

(i) A plan physician with privileges at the treating hospital assumes responsibility for the enrollee's care;

(ii) A plan physician assumes responsibility for the enrollee's care through transfer;

(iii) An M+C organization representative and the treating physician reach

an agreement concerning the enrollee's care; or

(iv) The enrollee is discharged.

[65 FR 40322, June 29, 2000]

§ 422.114 Access to services under an M+C private fee-for-service plan.

(a) *Sufficient access.* (1) An M+C organization that offers an M+C private fee-for-service plan must demonstrate to CMS that it has sufficient number and range of providers willing to furnish services under the plan.

(2) CMS finds that an M+C organization meets the requirement in paragraph (a)(1) of this section if, with respect to a particular category of health care providers, the M+C organization has—

(i) Payment rates that are not less than the rates that apply under original Medicare for the provider in question;

(ii) Contracts or agreements with a sufficient number and range of providers to furnish the services covered under the M+C private fee-for-service plan; or

(iii) A combination of paragraphs (a)(2)(i) and (a)(2)(ii) of this section.

(b) *Freedom of choice.* M+C fee-for-service plans must permit enrollees to obtain services from any entity that is authorized to provide services under Medicare Part A and Part B and agrees to provide services under the terms of the plan.

§ 422.118 Confidentiality and accuracy of enrollee records.

For any medical records or other health and enrollment information it maintains with respect to enrollees, an M+C organization must establish procedures to do the following:

(a) Abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. The M+C organization must safeguard the privacy of any information that identifies a particular enrollee and have procedures that specify—

(1) For what purposes the information will be used within the organization; and

(2) To whom and for what purposes it will disclose the information outside the organization.

(b) Ensure that medical information is released only in accordance with applicable Federal or State law, or pursuant to court orders or subpoenas.

(c) Maintain the records and information in an accurate and timely manner.

(d) Ensure timely access by enrollees to the records and information that pertain to them.

[65 FR 40323, June 29, 2000]

§ 422.128 Information on advance directives.

(a) Each M+C organization must maintain written policies and procedures that meet the requirements for advance directives, as set forth in subpart I of part 489 of this chapter. For purposes of this part, *advance directive* has the meaning given the term in § 489.100 of this chapter.

(b) An M+C organization must maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care by or through the M+C organization.

(1) An M+C organization must provide written information to those individuals with respect to the following:

(i) Their rights under the law of the State in which the organization furnishes services (whether statutory or recognized by the courts of the State) to make decisions concerning their medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives. Providers may contract with other entities to furnish this information but remain legally responsible for ensuring that the requirements of this section are met. The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the State law.

(ii) The M+C organization's written policies respecting the implementation of those rights, including a clear and precise statement of limitation if the M+C organization cannot implement an advance directive as a matter of conscience. At a minimum, this statement must do the following:

(A) Clarify any differences between institution-wide conscientious objections and those that may be raised by individual physicians.

(B) Identify the state legal authority permitting such objection.

(C) Describe the range of medical conditions or procedures affected by the conscience objection.

(D) Provide the information specified in paragraph (a)(1) of this section to each enrollee at the time of initial enrollment. If an enrollee is incapacitated at the time of initial enrollment and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, the M+C organization may give advance directive information to the enrollee's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated enrollee or to a surrogate or other concerned persons in accordance with State law. The M+C organization is not relieved of its obligation to provide this information to the enrollee once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to ensure that the information is given to the individual directly at the appropriate time.

(E) Document in a prominent part of the individual's current medical record whether or not the individual has executed an advance directive.

(F) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive.

(G) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives.

(H) Provide for education of staff concerning its policies and procedures on advance directives.

(I) Provide for community education regarding advance directives that may include material required in paragraph (a)(1)(i) of this section, either directly or in concert with other providers or entities. Separate community education materials may be developed and used, at the discretion of the M+C organization. The same written materials are not required for all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable State law concerning advance directives. An M+C organization must be able to document its community education efforts.

(2) The M+C organization—

(i) Is not required to provide care that conflicts with an advance directive; and

(ii) Is not required to implement an advance directive if, as a matter of conscience, the M+C organization cannot implement an advance directive and State law allows any health care provider or any agent of the provider to conscientiously object.

(3) The M+C organization must inform individuals that complaints concerning noncompliance with the advance directive requirements may be filed with the State survey and certification agency.

§ 422.132 Protection against liability and loss of benefits.

Enrollees of M+C organizations are entitled to the protections specified in § 422.502(g).

§ 422.133 Return to home skilled nursing facility.

(a) *General rule.* M+C plans must provide coverage of posthospital extended care services to Medicare enrollees through a home skilled nursing facility if the enrollee elects to receive the coverage through the home skilled nursing facility, and if the home skilled nursing facility either has a contract with the M+C organization or agrees to accept substantially similar payment under the same terms and conditions that apply to similar skilled nursing facilities that contract with the M+C organization.

(b) *Definitions.* In this subpart, *home skilled nursing facility* means—

(1) The skilled nursing facility in which the enrollee resided at the time of admission to the hospital preceding the receipt of posthospital extended care services;

(2) A skilled nursing facility that is providing posthospital extended care services through a continuing care retirement community in which the M+C

plan enrollee was a resident at the time of admission to the hospital. A continuing care retirement community is an arrangement under which housing and health-related services are provided (or arranged) through an organization for the enrollee under an agreement that is effective for the life of the enrollee or for a specified period; or

(3) The skilled nursing facility in which the spouse of the enrollee is residing at the time of discharge from the hospital.

(c) *Coverage no less favorable.* The posthospital extended care scope of services, cost-sharing, and access to coverage provided by the home skilled nursing facility must be no less favorable to the enrollee than posthospital extended care services coverage that would be provided to the enrollee by a skilled nursing facility that would be otherwise covered under the M+C plan.

(d) *Exceptions.* The requirement to allow an M+C plan enrollee to elect to return to the home skilled nursing facility for posthospital extended care services after discharge from the hospital does not do the following:

(1) Require coverage through a skilled nursing facility that is not otherwise qualified to provide benefits under Part A for Medicare beneficiaries not enrolled in the M+C plan.

(2) Prevent a skilled nursing facility from refusing to accept, or imposing conditions on the acceptance of, an enrollee for the receipt of posthospital extended care services.

[68 FR 50857, Aug. 22, 2003]

Subpart D—Quality Assurance

SOURCE: 63 FR 35082, June 26, 1998, unless otherwise noted.

§ 422.152 Quality assessment and performance improvement program.

(a) *General rule.* Each M+C organization that offers one or more M+C plans must have, for each of those plans, an ongoing quality assessment and performance improvement program that meets the applicable requirements of this section for the services it furnishes to its M+C enrollees.

(b) *Requirements for network M+C MSA plans and M+C coordinated care plans other than PPO plans.* An organization offering a network M+C MSA plan or M+C coordinated care plan other than a PPO plan must do the following:

(1) Meet the requirements in paragraph (c)(1) of this section concerning performance measurement and reporting. With respect to an M+C coordinated care plan, an organization must also meet the requirements of paragraph (c)(2) of this section concerning the achievement of minimum performance levels. The requirements of paragraph (c)(2) of this section do not apply with respect to an M+C MSA plan.

(2) Conduct performance improvement projects as described in paragraph (d) of this section. These projects must achieve, through ongoing measurement and intervention, demonstrable and sustained improvement in significant aspects of clinical care and nonclinical care areas that can be expected to have a favorable effect on health outcomes and enrollee satisfaction.

(3) In processing requests for initial or continued authorization of services, follow written policies and procedures that reflect current standards of medical practice.

(4) Have in effect mechanisms to detect both underutilization and overutilization of services.

(5) Make available to CMS information on quality and outcomes measures that will enable beneficiaries to compare health coverage options and select among them, as provided in § 422.64(c)(10).

(c) *Performance measurement and reporting.* The organization offering the plan must do the following:

(1) Measure performance under the plan, using standard measures required by CMS, and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS, and will relate to—

(i) Clinical areas including effectiveness of care, enrollee perception of care, and use of services; and

(ii) Nonclinical areas including access to and availability of services, appeals and grievances, and organizational characteristics.

(2) Achieve any minimum performance levels that CMS establishes locally, regionally, or nationally with respect to the standard measures.

(i) In establishing minimum performance levels, CMS considers historical plan and original Medicare performance data and trends.

(ii) CMS establishes the minimum performance levels prospectively upon contract initiation and renewal.

(iii) The organization must meet the minimum performance levels by the end of the contract year.

(iv) In accordance with §422.506, CMS may decline to renew the organization's contract in the year that CMS determines that it did not meet the minimum performance levels.

(d) *Performance improvement projects.* (1) Performance improvement projects are organization initiatives that focus on specified clinical and nonclinical areas and that involve the following:

(i) Measurement of performance.

(ii) System interventions, including the establishment or alteration of practice guidelines.

(iii) Improving performance.

(iv) Systematic follow-up on the effect of the interventions.

(2) Each project must address the entire population to which the measurement specified in paragraph (d)(1)(i) of this section is relevant.

(3) CMS establishes M+C organization and M+C plan-specific obligations for the number and distribution of projects among the required clinical and nonclinical areas, in accordance with paragraphs (d)(4) and (d)(5) of this section, to ensure that the projects are representative of the entire spectrum of clinical and nonclinical care areas associated with a plan.

(4) The required clinical areas include:

(i) Prevention and care of acute and chronic conditions.

(ii) High-volume services.

(iii) High-risk services.

(iv) Continuity and coordination of care.

(5) The required nonclinical areas include:

(i) Appeals, grievances, and other complaints.

(ii) Access to, and availability of, services.

(6) In addition to requiring that the organization initiate its own performance improvement projects, CMS may require that the organization—

(i) Conduct particular performance improvement projects that are specific to the organization; and

(ii) Participate in national or statewide performance improvement projects.

(7) For each project, the organization must assess performance under the plan using quality indicators that are—

(i) Objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research; and

(ii) Capable of measuring outcomes such as changes in health status, functional status and enrollee satisfaction, or valid proxies of those outcomes.

(8) Performance assessment on the selected indicators must be based on systematic ongoing collection and analysis of valid and reliable data.

(9) Interventions must achieve improvement that is significant and sustained over time.

(10) The organization must report the status and results of each project to CMS as requested.

(e) *Requirements for M+C PPO plans, non-network MSA plans, and M+C private fee-for-service plans.* An organization offering an M+C plan, non-network MSA plan, or private fee-for-service plan must do the following:

(1) Measure performance under the plan using standard measures required by CMS and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS and will relate to—

(i) Clinical areas including effectiveness of care, enrollee perception of care, and use of services; and

(ii) Nonclinical areas including access to and availability of services, appeals and grievances, and organizational characteristics.

(2) Evaluate the continuity and coordination of care furnished to enrollees.

(3) If the organization uses written protocols for utilization review, the organization must—

(i) Base those protocols on current standards of medical practice; and

(ii) Have mechanisms to evaluate utilization of services and to inform enrollees and providers of services of the results of the evaluation.

(f) *Requirements for all types of plans*—(1) *Health information.* For all types of plans that it offers, an organization must—

(i) Maintain a health information system that collects, analyzes, and integrates the data necessary to implement its quality assessment and performance improvement program;

(ii) Ensure that the information it receives from providers of services is reliable and complete; and

(iii) Make all collected information available to CMS.

(2) *Program review.* For each plan, there must be in effect a process for formal evaluation, at least annually, of the impact and effectiveness of its quality assessment and performance improvement program.

(3) *Remedial action.* For each plan, the organization must correct all problems that come to its attention through internal surveillance, complaints, or other mechanisms.

(4) *Focus on racial and ethnic minorities.* The M+C organization's Quality Assurance program must include a separate focus on racial and ethnic minorities.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40323, June 29, 2000; 68 FR 50857, Aug. 22, 2003]

§ 422.154 External review.

(a) *Basic rule.* Except as provided in paragraph (c) of this section, each M+C organization must, for each M+C plan it operates, have an agreement with an independent quality review and improvement organization (review organization) approved by CMS to perform functions of the type described in part 466 of this chapter.

(b) *Terms of the agreement.* The agreement must be consistent with CMS guidelines and include the following provisions:

(1) Require that the organization—

(i) Allocate adequate space for use of the review organization whenever it is conducting review activities; and

(ii) Provide all pertinent data, including patient care data, at the time the review organization needs the data to carry out the reviews and make its determinations.

(2) Except in the case of complaints about quality, exclude review activities that CMS determines would duplicate review activities conducted as part of an approved accreditation process or as part of CMS monitoring.

(c) *Exceptions.* The requirement of paragraph (a) of this section does not apply for an M+C private fee-for-service plan or a non-network M+C MSA plan if the organization does not carry out utilization review with respect to the plan.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40323, June 29, 2000]

§ 422.156 Compliance deemed on the basis of accreditation.

(a) *General rule.* An M+C organization is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(1) The M+C organization is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by CMS; and

(2) The accreditation organization used the standards approved by CMS for the purposes of assessing the M+C organization's compliance with Medicare requirements.

(b) *Deemable requirements.* The requirements relating to the following areas are deemable:

(1) Quality assurance.

(2) Antidiscrimination.

(3) Access to services.

(4) Confidentiality and accuracy of enrollee records.

(5) Information on advance directives.

(6) Provider participation rules.

(c) *Effective date of deemed status.* The date on which the organization is deemed to meet the applicable requirements is the later of the following:

(1) The date on which the accreditation organization is approved by CMS.

(2) The date the M+C organization is accredited by the accreditation organization.

(d) *Obligations of deemed M+C organizations.* An M+C organization deemed to meet Medicare requirements must—

(1) Submit to surveys by CMS to validate its accreditation organization's accreditation process; and

(2) Authorize its accreditation organization to release to CMS a copy of its most recent accreditation survey, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(e) *Removal of deemed status.* CMS removes part or all of an M+C organization's deemed status for any of the following reasons:

(1) CMS determines, on the basis of its own investigation, that the M+C organization does not meet the Medicare requirements for which deemed status was granted.

(2) CMS withdraws its approval of the accreditation organization that accredited the M+C organization.

(3) The M+C organization fails to meet the requirements of paragraph (d) of this section.

(f) *Enforcement authority.* CMS retains the authority to initiate enforcement action against any M+C organization that it determines, on the basis of its own survey or the results of an accreditation survey, no longer meets the Medicare requirements for which deemed status was granted.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40323, June 29, 2000; 65 FR 59749, Oct. 6, 2000]

§422.157 Accreditation organizations.

(a) *Conditions for approval.* CMS may approve an accreditation organization with respect to a given standard under this part if it meets the following conditions:

(1) In accrediting M+C organizations, it applies and enforces standards that are at least as stringent as Medicare requirements with respect to the standard or standards in question.

(2) It complies with the application and reapplication procedures set forth in §422.158.

(3) It ensures that:

(i) Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity.

(ii) The majority of the membership of its governing body is not comprised of managed care organizations or their representatives.

(iii) Its governing body has a broad and balanced representation of interests and acts without bias.

(b) *Notice and comment*—(1) *Proposed notice.* CMS publishes a notice in the FEDERAL REGISTER whenever it is considering granting an accreditation organization's application for approval. The notice—

(i) Announces CMS's receipt of the accreditation organization's application for approval;

(ii) Describes the criteria CMS will use in evaluating the application; and

(iii) Provides at least a 30-day comment period.

(2) *Final notice.* (i) After reviewing public comments, CMS publishes a final FEDERAL REGISTER notice indicating whether it has granted the accreditation organization's request for approval.

(ii) If CMS grants the request, the final notice specifies the effective date and the term of the approval, which may not exceed 6 years.

(c) *Ongoing responsibilities of an approved accreditation organization.* An accreditation organization approved by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS in written form and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to deemed M+C organizations.

(iv) Information about any M+C organization against which the accrediting organization has taken remedial or adverse action, including revocation, withdrawal or revision of the M+C organization's accreditation. (The accreditation organization must provide this information within 30 days of taking the remedial or adverse action.)

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before

or without CMS approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 days of a change in CMS requirements, submit to CMS—

(i) An acknowledgment of CMS's notification of the change;

(ii) A revised cross-walk reflecting the new requirements; and

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to CMS's new requirements, within the time-frames specified in the notification of change it receives from CMS.

(3) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 3 days of identifying, in an accredited M+C organization, a deficiency that poses immediate jeopardy to the organization's enrollees or to the general public, give CMS written notice of the deficiency.

(5) Within 10 days of CMS's notice of withdrawal of approval, give written notice of the withdrawal to all accredited M+C organizations.

(6) Provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(d) *Continuing Federal oversight of approved accreditation organizations.* This paragraph establishes specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization.

(1) *Equivalency review.* CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation review.* CMS or its agent may conduct a survey of an accredited organization, examine the results of the accreditation organization's own survey, or attend the accreditation organization's survey, in order to validate the organization's accreditation process. At the conclusion of the review, CMS identifies any accreditation programs for which validation survey results—

(i) Indicate a 20 percent rate of disparity between certification by the accreditation organization and certification by CMS or its agent on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

(ii) Indicate any disparity between certification by the accreditation organization and certification by CMS or its agent on standards that constitute immediate jeopardy to patient health and safety if unmet; or

(iii) Indicate that, irrespective of the rate of disparity, there are widespread or systematic problems in an organization's accreditation process such that accreditation no longer provides assurance that the Medicare requirements are met or exceeded.

(3) *Onsite observation.* CMS may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, reviewing documents, auditing meetings concerning the accreditation process, evaluating survey results or the accreditation status decision making process, and interviewing the organization's staff.

(4) *Notice of intent to withdraw approval.* If an equivalency review, validation review, onsite observation, or CMS's daily experience with the accreditation organization suggests that the accreditation organization is not meeting the requirements of this subpart, CMS gives the organization written notice of its intent to withdraw approval.

(5) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Deeming based on accreditation no longer guarantees that the M+C organization meets the M+C requirements, and failure to meet those requirements could jeopardize the health or safety of Medicare enrollees and constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations under this section or under §422.156 or §422.158.

(6) *Reconsideration of withdrawal of approval.* An accreditation organization dissatisfied with a determination to withdraw CMS approval may request a reconsideration of that determination in accordance with subpart D of part 488 of this chapter.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40323, June 29, 2000; 65 FR 59749, Oct. 6, 2000]

§422.158 Procedures for approval of accreditation as a basis for deeming compliance.

(a) *Required information and materials.* A private, national accreditation organization applying for approval must furnish to CMS all of the following information and materials. (When reapplying for approval, the organization need furnish only the particular information and materials requested by CMS.)

(1) The types of M+C plans that it would review as part of its accreditation process.

(2) A detailed comparison of the organization's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk).

(3) Detailed information about the organization's survey process, including—

(i) Frequency of surveys and whether surveys are announced or unannounced.

(ii) Copies of survey forms, and guidelines and instructions to surveyors.

(iii) Descriptions of—

(A) The survey review process and the accreditation status decision making process;

(B) The procedures used to notify accredited M+C organizations of deficiencies and to monitor the correction of those deficiencies; and

(C) The procedures used to enforce compliance with accreditation requirements.

(4) Detailed information about the individuals who perform surveys for the accreditation organization, including—

(i) The size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process;

(ii) The education and experience requirements surveyors must meet;

(iii) The content and frequency of the in-service training provided to survey personnel;

(iv) The evaluation systems used to monitor the performance of individual surveyors and survey teams; and

(v) The organization's policies and practice with respect to the participation, in surveys or in the accreditation decision process by an individual who is professionally or financially affiliated with the entity being surveyed.

(5) A description of the organization's data management and analysis system with respect to its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(6) A description of the organization's procedures for responding to and investigating complaints against accredited organizations, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.

(7) A description of the organization's policies and procedures with respect to the withholding or removal of accreditation for failure to meet the accreditation organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

(8) A description of all types (for example, full, partial) and categories (for example, provisional, conditional, temporary) of accreditation offered by the organization, the duration of each type and category of accreditation and a statement identifying the types and categories that would serve as a basis for accreditation if CMS approves the accreditation organization.

(9) A list of all currently accredited M+C organizations and the type, category, and expiration date of the accreditation held by each of them.

(10) A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization as requested by CMS.

(11) The name and address of each person with an ownership or control interest in the accreditation organization.

(b) *Required supporting documentation.* A private, national accreditation organization applying or reapplying for approval must also submit the following supporting documentation:

(1) A written presentation that demonstrates its ability to furnish CMS with electronic data in CMS compatible format.

(2) A resource analysis that demonstrates that its staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(3) A statement acknowledging that, as a condition for approval, it agrees to comply with the ongoing responsibility requirements of § 422.157(c).

(c) *Additional information.* If CMS determines that it needs additional information for a determination to grant or deny the accreditation organization's request for approval, it notifies the organization and allows time for the organization to provide the additional information.

(d) *Onsite visit.* CMS may visit the accreditation organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents, and interviews with the organization's staff.

(e) *Notice of determination.* CMS gives the accreditation organization, within 210 days of receipt of its completed application, a formal notice that—

(1) States whether the request for approval has been granted or denied;

(2) Gives the rationale for any denial; and

(3) Describes the reconsideration and reapplication procedures.

(f) *Withdrawal.* An accreditation organization may withdraw its application for approval at any time before it receives the formal notice specified in paragraph (e) of this section.

(g) *Reconsideration of adverse determination.* An accreditation organization that has received notice of denial of its request for approval may request reconsideration in accordance with subpart D of part 488 of this chapter.

(h) *Request for approval following denial.* (1) Except as provided in paragraph (h)(2) of this section, an accreditation organization that has received notice of denial of its request for approval may submit a new request if it—

(i) Has revised its accreditation program to correct the deficiencies on which the denial was based;

(ii) Can demonstrate that the M+C organizations that it has accredited meet or exceed applicable Medicare requirements; and

(iii) Resubmits the application in its entirety.

(2) An accreditation organization that has requested reconsideration of CMS's denial of its request for approval may not submit a new request until the reconsideration is administratively final.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40324, June 29, 2000]

Subpart E—Relationships With Providers

SOURCE: 63 FR 35085, June 26, 1998, unless otherwise noted.

§ 422.200 Basis and scope.

This subpart is based on sections 1852(a)(1), (a)(2), (b)(2), (c)(2)(D), (j), and (k) of the Act; section 1859(b)(2)(A) of the Act; and the general authority under 1856(b) of the Act requiring the establishment of standards. It sets forth the requirements and standards for the M+C organization's relationships with providers including physicians, other health care professionals, institutional providers and suppliers, under contracts or arrangements or deemed contracts under M+C private fee-for-service plans. This subpart also contains some requirements that apply to noncontracting providers.

§ 422.202 Participation procedures.

(a) *Notice and appeal rights.* An M+C organization that operates a coordinated care plan or network MSA plan must provide for the participation of individual physicians, and the management and members of groups of physicians, through reasonable procedures that include the following:

(1) Written notice of rules of participation including terms of payment, credentialing, and other rules directly related to participation decisions.

(2) Written notice of material changes in participation rules before the changes are put into effect.

(3) Written notice of participation decisions that are adverse to physicians.

(4) A process for appealing adverse participation procedures, including the right of physicians to present information and their views on the decision. In the case of termination or suspension of a provider contract by the M+C organization, this process must conform to the rules in § 422.202(d).

(b) *Consultation.* The M+C organization must establish a formal mechanism to consult with the physicians who have agreed to provide services under the M+C plan offered by the organization, regarding the organization's medical policy, quality assurance programs and medical management procedures and ensure that the following standards are met:

(1) Practice guidelines and utilization management guidelines—

(i) Are based on reasonable medical evidence or a consensus of health care professionals in the particular field;

(ii) Consider the needs of the enrolled population;

(iii) Are developed in consultation with contracting physicians; and

(iv) Are reviewed and updated periodically.

(2) The guidelines are communicated to providers and, as appropriate, to enrollees.

(3) Decisions with respect to utilization management, enrollee education, coverage of services, and other areas in which the guidelines apply are consistent with the guidelines.

(c) *Subcontracted groups.* An M+C organization that operates an M+C plan through subcontracted physician groups must provide that the participation procedures in this section apply equally to physicians within those subcontracted groups.

(d) *Suspension or termination of contract.* An M+C organization that operates a coordinated care plan or network MSA plan providing benefits through contracting providers must meet the following requirements:

(1) *Notice to physician.* An M+C organization that suspends or terminates an agreement under which the physician provides services to M+C plan enrollees must give the affected individual written notice of the following:

(i) The reasons for the action, including, if relevant, the standards and profiling data used to evaluate the physician and the numbers and mix of physicians needed by the M+C organization.

(ii) The affected physician's right to appeal the action and the process and timing for requesting a hearing.

(2) *Composition of hearing panel.* The M+C organization must ensure that the majority of the hearing panel members are peers of the affected physician.

(3) *Notice to licensing or disciplinary bodies.* An M+C organization that suspends or terminates a contract with a physician because of deficiencies in the quality of care must give written notice of that action to licensing or disciplinary bodies or to other appropriate authorities.

(4) *Timeframes.* An M+C organization and a contracting provider must provide at least 60 days written notice to each other before terminating the contract without cause.

[64 FR 7981, Feb. 17, 1999, as amended at 65 FR 40324, June 29, 2000; 68 FR 50857, Aug. 22, 2003]

§ 422.204 Provider selection and credentialing.

(a) *General rule.* An M+C organization must have written policies and procedures for the selection and evaluation of providers. These policies must conform with the credential and recredentialing requirements set forth in paragraph (b) of this section and with the antidiscrimination provisions set forth in § 422.205.

(b) *Basic requirements.* An M+C organization must follow a documented process with respect to providers and suppliers who have signed contracts or participation agreements that—

(1) For providers (other than physicians and other health care professionals) requires determination, and redetermination at specified intervals, that each provider is—

(i) Licensed to operate in the State, and in compliance with any other applicable State or Federal requirements; and

(ii) Reviewed and approved by an accrediting body, or meets the standards established by the organization itself;

(2) For physicians and other health care professionals, including members of physician groups, covers—

(i) Initial credentialing that includes written application, verification of licensure or certification from primary sources, disciplinary status, eligibility for payment under Medicare, and site visits as appropriate. The application must be signed and dated and include an attestation by the applicant of the correctness and completeness of the application and other information submitted in support of the application;

(ii) Recredentialing at least every 3 years that updates information obtained during initial credentialing, considers performance indicators such as those collected through quality assurance programs, utilization management systems, handling of grievances and appeals, enrollee satisfaction surveys, and other plan activities, and that includes an attestation of the correctness and completeness of the new information; and

(iii) A process for consulting with contracting health care professionals with respect to criteria for credentialing and recredentialing.

(3) Specifies that basic benefits must be provided through, or payments must be made to, providers and suppliers that meet applicable requirements of title XVIII and part A of title XI of the Act. In the case of providers meeting the definition of "provider of services" in section 1861(u) of the Act, basic benefits may only be provided through these providers if they have a provider agreement with CMS permitting them to provide services under original Medicare.

(4) Ensures compliance with the requirements at §422.752(a)(8) that prohibit employment or contracts with individuals (or with an entity that employs or contracts with such an individual) excluded from participation under Medicare and with the requirements at §422.220 regarding physicians and practitioners who opt out of Medicare.

[65 FR 40324, June 29, 2000, as amended at 66 FR 47413, Sept. 12, 2001]

§422.205 Provider antidiscrimination rules.

(a) *General rule.* Consistent with the requirements of this section, the policies and procedures concerning provider selection and credentialing established under §422.204, and with the requirement under §422.100(c) that all Medicare-covered services be available to M+C plan enrollees, an M+C organization may select the practitioners that participate in its plan provider networks. In selecting these practitioners, an M+C organization may not discriminate, in terms of participation, reimbursement, or indemnification, against any health care professional who is acting within the scope of his or her license or certification under State law, solely on the basis of the license or certification. If an M+C organization declines to include a given provider or group of providers in its network, it must furnish written notice to the effected provider(s) of the reason for the decision.

(b) *Construction.* The prohibition in paragraph (a)(1) of this section does not preclude any of the following by the M+C organization:

(1) Refusal to grant participation to health care professionals in excess of the number necessary to meet the needs of the plan's enrollees (except for M+C private-fee-for-service plans, which may not refuse to contract on this basis).

(2) Use of different reimbursement amounts for different specialties or for different practitioners in the same specialty.

(3) Implementation of measures designed to maintain quality and control costs consistent with its responsibilities.

[65 FR 40324, June 29, 2000]

§422.206 Interference with health care professionals' advice to enrollees prohibited.

(a) *General rule.* (1) An M+C organization may not prohibit or otherwise restrict a health care professional, acting within the lawful scope of practice,

from advising, or advocating on behalf of, an individual who is a patient and enrolled under an M+C plan about—

(i) The patient's health status, medical care, or treatment options (including any alternative treatments that may be self-administered), including the provision of sufficient information to the individual to provide an opportunity to decide among all relevant treatment options;

(ii) The risks, benefits, and consequences of treatment or non-treatment; or

(iii) The opportunity for the individual to refuse treatment and to express preferences about future treatment decisions.

(2) Health care professionals must provide information regarding treatment options in a culturally-competent manner, including the option of no treatment. Health care professionals must ensure that individuals with disabilities have effective communications with participants throughout the health system in making decisions regarding treatment options.

(b) *Conscience protection.* The general rule in paragraph (a) of this section does not require the M+C plan to cover, furnish, or pay for a particular counseling or referral service if the M+C organization that offers the plan—

(1) Objects to the provision of that service on moral or religious grounds; and

(2) Through appropriate written means, makes available information on these policies as follows:

(i) To CMS, with its application for a Medicare contract, within 10 days of submitting its ACR proposal or, for policy changes, in accordance with §422.80 (concerning approval of marketing materials and election forms) and with §422.111.

(ii) To prospective enrollees, before or during enrollment.

(iii) With respect to current enrollees, the organization is eligible for the exception provided in paragraph (b)(1) of this section if it provides notice of such change within 90 days after adopting the policy at issue; however, under §422.111(d), notice of such a change must be given in advance.

(c) *Construction.* Nothing in paragraph (b) of this section may be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974.

(d) *Sanctions.* An M+C organization that violates the prohibition of paragraph (a) of this section or the conditions in paragraph (b) of this section is subject to intermediate sanctions under subpart O of this part.

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000]

§ 422.208 Physician incentive plans: requirements and limitations.

(a) *Definitions.* In this subpart, the following definitions apply:

Bonus means a payment made to a physician or physician group beyond any salary, fee-for-service payments, capitation, or returned withhold.

Capitation means a set dollar payment per patient per unit of time (usually per month) paid to a physician or physician group to cover a specified set of services and administrative costs without regard to the actual number of services provided. The services covered may include the physician's own services, referral services, or all medical services.

Physician group means a partnership, association, corporation, individual practice association, or other group of physicians that distributes income from the practice among members. An individual practice association is defined as a physician group for this section only if it is composed of individual physicians and has no subcontracts with physician groups.

Physician incentive plan means any compensation arrangement to pay a physician or physician group that may directly or indirectly have the effect of reducing or limiting the services provided to any plan enrollee.

Potential payments means the maximum payments possible to physicians or physician groups including payments for services they furnish directly, and additional payments based on use and costs of referral services, such as withholds, bonuses, capitation, or any other compensation to the physician or physician group. Bonuses and other compensation that are not based on use of referrals, such as quality of care furnished, patient satisfaction or

committee participation, are not considered payments in the determination of substantial financial risk.

Referral services means any specialty, inpatient, outpatient, or laboratory services that a physician or physician group orders or arranges, but does not furnish directly.

Risk threshold means the maximum risk, if the risk is based on referral services, to which a physician or physician group may be exposed under a physician incentive plan without being at substantial financial risk. This is set at 25 percent risk.

Substantial financial risk, for purposes of this section, means risk for referral services that exceeds the risk threshold.

Withhold means a percentage of payments or set dollar amounts deducted from a physician's service fee, capitation, or salary payment, and that may or may not be returned to the physician, depending on specific predetermined factors.

(b) *Applicability.* The requirements in this section apply to an M+C organization and any of its subcontracting arrangements that utilize a physician incentive plan in their payment arrangements with individual physicians or physician groups. Subcontracting arrangements may include an intermediate entity, which includes but is not limited to, an individual practice association that contracts with one or more physician groups or any other organized group such as those specified in § 422.4.

(c) *Basic requirements.* Any physician incentive plan operated by an M+C organization must meet the following requirements:

(1) The M+C organization makes no specific payment, directly or indirectly, to a physician or physician group as an inducement to reduce or limit medically necessary services furnished to any particular enrollee. Indirect payments may include offerings of monetary value (such as stock options or waivers of debt) measured in the present or future.

(2) If the physician incentive plan places a physician or physician group at substantial financial risk (as determined under paragraph (d) of this section) for services that the physician or physician group does not furnish itself, the M+C organization must assure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection in accordance with paragraph (f) of this section, and conduct periodic surveys in accordance with paragraph (h) of this section.

(3) For all physician incentive plans, the M+C organization provides to CMS the information specified in § 422.210.

(d) *Determination of substantial financial risk*—(1) *Basis.* Substantial financial risk occurs when risk is based on the use or costs of referral services, and that risk exceeds the risk threshold. Payments based on other factors, such as quality of care furnished, are not considered in this determination.

(2) *Risk threshold.* The risk threshold is 25 percent of potential payments.

(3) *Arrangements that cause substantial financial risk.* The following incentive arrangements cause substantial financial risk within the meaning of this section, if the physician's or physician group's patient panel size is not greater than 25,000 patients, as shown in the table at paragraph (f)(2)(iii) of this section:

(i) Withholds greater than 25 percent of potential payments.

(ii) Withholds less than 25 percent of potential payments if the physician or physician group is potentially liable for amounts exceeding 25 percent of potential payments.

(iii) Bonuses that are greater than 33 percent of potential payments minus the bonus.

(iv) Withholds plus bonuses if the withholds plus bonuses equal more than 25 percent of potential payments. The threshold bonus percentage for a particular withhold percentage may be calculated using the formula—Withhold % = −0.75 (Bonus %) +25%.

(v) Capitation arrangements, if—

(A) The difference between the maximum potential payments and the minimum potential payments is more than 25 percent of the maximum potential payments;

(B) The maximum and minimum potential payments are not clearly explained in the contract with the physician or physician group.

(vi) Any other incentive arrangements that have the potential to hold a physician or physician group liable for more than 25 percent of potential payments.

(e) *Prohibition for private M+C fee-for-service plans.* An M+C fee-for-service plan may not operate a physician incentive plan.

(f) *Stop-loss protection requirements*—(1) *Basic rule.* The M+C organization must assure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection in accordance with the following requirements:

(2) *Specific requirements.* (i) Aggregate stop-loss protection must cover 90 percent of the costs of referral services that exceed 25 percent of potential payments.

(ii) For per-patient stop-loss protection if the stop-loss protection provided is on a per-patient basis, the stop-loss limit (deductible) per patient must be determined based on the size of the patient panel and may be a combined policy or consist of separate policies for professional services and institutional services. In determining patient panel size, the patients may be pooled in accordance with paragraph (g) of this section.

(iii) Stop-loss protection must cover 90 percent of the costs of referral services that exceed the per patient deductible limit. The per-patient stop-loss deductible limits are as follows:

Panel size	Single combined deductible	Separate institutional deductible	Separate professional deductible
1–1,000	$6,000	$10,000	$3,000
1,001–5,000	30,000	40,000	10,000
5,001–8,000	40,000	60,000	15,000
8,001–10,000	75,000	100,000	20,000
10,001–25,000	150,000	200,000	25,000
>25,000	[1]	[1]	[1]

[1] None.

(g) *Pooling of patients.* Any entity that meets the pooling conditions of this section may pool commercial, Medicare, and Medicaid enrollees or the enrollees of several M+C organizations with which a physician or physician group has contracts. The conditions for pooling are as follows:

(1) It is otherwise consistent with the relevant contracts governing the compensation arrangements for the physician or physician group.

(2) The physician or physician group is at risk for referral services with respect to each of the categories of patients being pooled.

(3) The terms of the compensation arrangements permit the physician or physician group to spread the risk across the categories of patients being pooled.

(4) The distribution of payments to physicians from the risk pool is not calculated separately by patient category.

(5) The terms of the risk borne by the physician or physician group are comparable for all categories of patients being pooled.

(h) *Periodic surveys of current and former enrollees.* An M+C organization must conduct periodic surveys of current and former enrollees where substantial financial risk exists. These periodic surveys must—

(1) Include either a sample of, or all, current Medicare/Medicaid enrollees in the M+C organization and individuals disenrolled in the past 12 months for reasons other than—

(i) The loss of Medicare or Medicaid eligibility;

(ii) Relocation outside the M+C organization's service area;

(iii) For failure to pay premiums or other charges;

(iv) For abusive behavior; and

(v) Retroactive disenrollment.

(2) Be designed, implemented, and analyzed in accordance with commonly accepted principles of survey design and statistical analysis;

(3) Measure the degree of enrollees/disenrollees' satisfaction with the quality of the services provided and the degree to which the enrollees/disenrollees have or had access to the services provided under the M+C organization; and

(4) Be conducted no later than 1 year after the effective date of the M+C organization's contract and at least annually thereafter.

(i) *Sanctions.* An M+C organization that fails to comply with the requirements of this section is subject to intermediate sanctions under subpart O of this part.

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000]

§ 422.210 Disclosure of physician incentive plans.

(a) *Disclosure to CMS.* Each M+C organization must provide to CMS information concerning its physician incentive plans as requested.

(b) *Disclosure to Medicare beneficiaries.* Each M+C organization must provide the following information to any Medicare beneficiary who requests it:

(1) Whether the M+C organization uses a physician incentive plan that affects the use of referral services.

(2) The type of incentive arrangement.

(3) Whether stop-loss protection is provided.

(4) If the M+C organization was required to conduct a survey, a summary of the survey results.

[63 FR 35085, June 26, 1998, as amended at 68 FR 50858, Aug. 22, 2003]

§ 422.212 Limitations on provider indemnification.

An M+C organization may not contract or otherwise provide, directly or indirectly, for any of the following individuals, organizations, or entities to indemnify the organization against any civil liability for damage caused to an enrollee as a result of the M+C organization's denial of medically necessary care:

(a) A physician or health care professional.

(b) Provider of services.

(c) Other entity providing health care services.

(d) Group of such professionals, providers, or entities.

§ 422.214 Special rules for services furnished by noncontract providers.

(a) *Services furnished by non-section 1861(u) providers.* (1) Any provider (other than a provider of services as defined in section 1861(u) of the Act) that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an M+C coordinated care plan or M+C private fee-for-service plan must accept, as payment in full, the amounts that the provider could collect if the beneficiary were enrolled in original Medicare.

(2) Any statutory provisions (including penalty provisions) that apply to payment for services furnished to a beneficiary not enrolled in an M+C plan also apply to the payment described in paragraph (a)(1) of this section.

(b) *Services furnished by section 1861(u) providers of service.* Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an M+C coordinated care plan or M+C private fee-for-service plan must accept as payment in full the amounts (less any payments under §§412.105(g) and 413.86(d)) of this chapter that it could collect if the beneficiary were enrolled in original Medicare. (Section 412.105(g) concerns indirect medical education payment to hospitals for managed care enrollees. Section 413.86(d) concerns calculating payment for direct graduate medical education costs.)

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000]

§ 422.216 Special rules for M+C private fee-for-service plans.

(a) *Payment to providers*—(1) *Payment rate.* (i) The M+C organization must establish uniform payment rates for items and services that apply to all contracting providers, regardless of whether the contract is signed or deemed under paragraph (f) of this section.

(ii) Contracting providers must be reimbursed on a fee-for-service basis.

(iii) The M+C organization must make information on its payment rates available to providers that furnish services that may be covered under the M+C private fee-for-service plan.

(2) *Payment to contract providers.* For each service, the M+C organization pays a contract provider (including one

deemed to have a contract) an amount that is equal to the payment rate under paragraph (a)(1) of this section minus any applicable cost-sharing.

(3) *Noncontract providers.* The organization pays for services of noncontract providers in accordance with §422.100(b)(2).

(4) *Service furnished by providers of service.* Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment mounts for services furnished to a beneficiary enrolled in an M+C private fee-for-service plan must accept as payment in full the amounts (less any payments under §§412.105(g) and 413.86(d) of this chapter) that it could collect if the beneficiary were enrolled in original Medicare.

(b) *Charges to enrollees*—(1) *Contract providers.* (i) Contract providers and "deemed" contract providers may charge enrollees no more than the cost-sharing and, subject to the limit in paragraph (b)(1)(ii) of this section, balance billing amounts that are permitted under the plan, and these amounts must be the same for "deemed" contract providers as for those that have signed contracts in effect.

(ii) The organization may permit balance billing no greater than 15 percent of the payment rate established under paragraph (a)(1) of this section.

(iii) The M+C organization must specify the amount of cost-sharing and balance billing in its contracts with providers and these amounts must be the same for "deemed" contract providers as for those that have signed contracts in effect.

(iv) The M+C organization is subject to intermediate sanctions under §422.752(a)(7), under the rules in subpart O of this part, if it fails to enforce the limit specified in paragraph (b)(1)(i) of this section.

(2) *Noncontract providers.* A noncontract provider may not collect from an enrollee more than the cost-sharing established by the M+C private fee-for-service plan as specified in §422.308(b), unless the provider has opted out of Medicare as described in part 405, subpart D of this chapter.

(c) *Enforcement of limit*—(1) *Contract providers.* An M+C organization that offers an M+C fee-for-service plan must enforce the limit specified in paragraph (b)(1) of this section.

(2) *Noncontract providers.* An M+C organization that offers an M+C private fee-for-service plan must monitor the amount collected by noncontract providers to ensure that those amounts do not exceed the amounts permitted to be collected under paragraph (b)(2) of this section, unless the provider has opted out of Medicare as described in part 405, subpart D of this chapter. The M+C organization must develop and document violations specified in instructions and must forward documented cases to CMS.

(d) *Information on enrollee liability*—(1) *General information.* An M+C organization that offers an M+C fee-for-service plan must provide to plan enrollees, for each claim filed by the enrollee or the provider that furnished the service, an appropriate explanation of benefits. The explanation must include a clear statement of the enrollee's liability for deductibles, coinsurance, copayment, and balance billing.

(2) *Advance notice for hospital services.* In its terms and conditions of payment to hospitals, the M+C organization must require the hospital, if it imposes balance billing, to provide to the enrollee, before furnishing any services for which balance billing could amount to not less than $500—

(i) Notice that balance billing is permitted for those services;

(ii) A good faith estimate of the likely amount of balance billing, based on the enrollees presenting condition; and

(iii) The amount of any deductible, coinsurance, and copayment that may be due in addition to the balance billing amount.

(e) *Coverage determinations.* The M+C organization must make coverage determinations in accordance with subpart M of this part.

(f) *Rules describing deemed contract providers.* Any provider furnishing health services, except for emergency services furnished in a hospital pursuant to §489.24 of this chapter, to an enrollee in an M+C private fee-for-service plan, and who has not previously entered into a contract or agreement to

furnish services under the plan, is treated as having a contract in effect and is subject to the limitations of this section that apply to contract providers if the following conditions are met:

(1) The services are covered under the plan and are furnished—

(i) To an enrollee of an M+C fee-for-service plan; and

(ii) Provided by a provider including a provider of services (as defined in section 1861(u) of the Act) that does not have in effect a signed contract with the M+C organization.

(2) Before furnishing the services, the provider—

(i) Was informed of the individual's enrollment in the plan; and

(ii) Was informed (or given a reasonable opportunity to obtain information) about the terms and conditions of payment under the plan, including the information described in §422.202(a)(1).

(3) The information was provided in a manner that was reasonably designed to effect informed agreement and met the requirements of paragraphs (g) and (h) of this section.

(g) *Enrollment information.* Enrollment information was provided by one of the following methods or a similar method:

(1) Presentation of an enrollment card or other document attesting to enrollment.

(2) Notice of enrollment from CMS, a Medicare intermediary or carrier, or the M+C organization itself.

(h) *Information on payment terms and conditions.* Information on payment terms and conditions was made available through either of the following methods:

(1) The M+C organization used postal service, electronic mail, FAX, or telephone to communicate the information to one of the following:

(i) The provider.

(ii) The employer or billing agent of the provider.

(iii) A partnership of which the provider is a member.

(iv) Any party to which the provider makes assignment or reassigns benefits.

(2) The M+C organization has in effect a procedure under which—

(i) Any provider furnishing services to an enrollee in an M+C private fee-for-service plan, and who has not previously entered into a contract or agreement to furnish services under the plan, can receive instructions on how to request the payment information;

(ii) The organization responds to the request before the entity furnishes the service; and

(iii) The information the organization provides includes the following:

(A) Billing procedures.

(B) The amount the organization will pay towards the service.

(C) The amount the provider is permitted to collect from the enrollee.

(D) The information described in §422.202(a)(1).

(3) Announcements in newspapers, journals, or magazines or on radio or television are not considered communication of the terms and conditions of payment.

(i) *Provider credentialing requirements.* Contracts with providers must provide that, in order to be paid to provide services to plan enrollees, providers must meet the requirements specified in §422.204(a)(1) and (a)(1)(iii).

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000]

§422.220 Exclusion of services furnished under a private contract.

An M+C organization may not pay, directly or indirectly, on any basis, for services (other than emergency or urgently needed services as defined in §422.2) furnished to a Medicare enrollee by a physician (as defined in section 1861(r)(1) of the Act) or other practitioner (as defined in section 1842(b)(18)(C) of the Act) who has filed with the Medicare carrier an affidavit promising to furnish Medicare-covered services to Medicare beneficiaries only through private contracts under section 1802(b) of the Act with the beneficiaries. An M+C organization must pay for emergency or urgently needed services furnished by a physician or practitioner who has not signed a private contract with the beneficiary.

Subpart F—Payments to Medicare+Choice Organizations

SOURCE: 63 FR 35090, June 26, 1998, unless otherwise noted.

§422.249 Terminology.

In this subpart—

(a) The terms "per capita rate" and "capitation rate" (see §422.252) are used interchangeably; and

(b) In the term "area-specific," "area" refers to any of the payment areas described in §422.250(c).

§422.250 General provisions.

(a) *Monthly payments*—(1) *General rule.* (i) Except as provided in paragraphs (a)(2) or (f) of this section, CMS makes advance monthly payments equal to 1/12th of the annual M+C capitation rate for the payment area described in paragraph (c) of this section adjusted for such demographic risk factors as an individual's age, disability status, sex, institutional status, and other factors as it determines to be appropriate to ensure actuarial equivalence.

(ii) Effective January 1, 2000, CMS adjusts for health status as provided in §422.256(c). When the new risk adjustment is implemented, 1/12th of the annual capitation rate for the payment area described in paragraph (c) of this section will be adjusted by the risk adjustment methodology under §422.256(d).

(iii) Effective January 1, 2003, monthly payments may be reduced by the adjusted excess amount, as described in §422.312(a)(2), and 80 percent of the reduction in monthly payments used to reduce the Medicare beneficiary's Part B premium, up to a total of 125 percent of Part B premium amount.

(2) *Special rules*—(i) *Enrollees with end-stage renal disease.* (A) For enrollees determined to have end-stage renal disease (ESRD), CMS establishes special rates that are determined under an actuarially equivalent approach to that used in establishing the rates under original Medicare.

(B) CMS applies appropriate adjustments when establishing the rates, including risk adjustment factors. CMS also establishes annual changes in capitation rates using the methodology described in §422.252. Effective 2002, a special adjustment is made to increase ESRD rates to 100 percent of estimated per capita fee-for-service expenditures and rates are adjusted for age and sex. In subsequent years, rates are adjusted for age, sex, and other factors, if appropriate.

(C) CMS reduces the payment rate for each renal dialysis treatment by the same amount that the Secretary is authorized to reduce the amount of each composite rate payment for each treatment as set forth in section 1881(b)(7) of the Act. These funds are to be used to help pay for the ESRD network program in the same manner as similar reductions are used in original Medicare.

(ii) *MSA enrollees.* For MSA enrollees, CMS makes advanced monthly payments as described in paragraph (a)(1) less the amount (if any) identified in §422.262(c)(1)(ii) to be deposited in the M+C MSA. In addition, CMS deposits in the M+C MSA the lump sum amounts (if any) determined in accordance with §422.262(c).

(iii) *RFB plan enrollees.* For RFB plan enrollees, CMS adjusts the capitation payments otherwise determined under this subpart to ensure that the payment level is appropriate for the actuarial characteristics and experience of these enrollees. Such adjustment can be made on an individual or organization basis.

(b) *Adjustment of payments to reflect number of Medicare enrollees*—(1) *General rule.* CMS adjusts payments retroactively to take into account any difference between the actual number of Medicare enrollees and the number on which it based an advance monthly payment.

(2) *Special rules for certain enrollees.* (i) Subject to paragraph (b)(2)(ii) of this section, CMS may make adjustments, for a period (not to exceed 90 days) that begins when a beneficiary elects a group health plan (as defined in §411.101 of this chapter) offered by an M+C organization, and ends when the beneficiary is enrolled in an M+C plan offered by the M+C organization.

(ii) CMS does not make an adjustment unless the beneficiary certifies that, at the time of enrollment under the M+C plan, he or she received from

the organization the disclosure statement specified in § 422.111.

(c) *Payment areas*—(1) *General rule.* Except as provided in paragraph (e) of this section, the M+C payment area is a county or an equivalent geographic area specified by CMS.

(2) *Special rule for ESRD enrollees.* For ESRD enrollees, the M+C payment area is a State or other geographic area specified by CMS.

(d) *Terminology.* As used in paragraph (e) of this section, "metropolitan statistical area," "consolidated metropolitan statistical area," and "primary metropolitan statistical area" mean any areas so designated by the Secretary of Commerce.

(e) *Geographic adjustment of payment areas.* For contract years beginning after 1999—

(1) *State request.* A State's chief executive may request, no later than February 1 of any year, a geographic adjustment of the State's payment areas for the following calendar year. The chief executive may request any of the following adjustments to the payment area specified in paragraph (c)(1) of this section:

(i) A single Statewide M+C payment area.

(ii) A metropolitan-based system in which all nonmetropolitan areas within the State constitute a single payment area and any of the following constitutes a separate M+C payment area:

(A) All portions of each single metropolitan statistical area within the State.

(B) All portions of each primary metropolitan statistical area within each consolidated metropolitan statistical area within the State.

(iii) A consolidation of noncontiguous counties.

(2) *CMS response.* In response to the request, CMS makes the payment adjustment requested by the chief executive.

(3) *Budget neutrality adjustment for geographically adjusted payment areas.* If CMS adjusts a State's payment areas in accordance with paragraph (e)(2) of this section, CMS at that time, and each year thereafter, adjusts the capitation rates so that the aggregate Medicare payments do not exceed the aggregate Medicare payments that would have been made to all the State's payments areas, absent the geographic adjustment.

(f) *Determination and applicability of payment rates.* (1) All payment rates are annual rates, determined and promulgated no later than March 1st, for the following calendar year.

(2) For purposes of paragraphs (b) and (c) of § 422.252, except as provided in § 422.254(e)(4), the "capitation payment rate for 1997" is the rate determined under section 1876(a)(1)(c) of the Act.

(g) *Bonus payments.* (1) CMS provides bonus payments to the M+C organization(s) that first offers a plan in a previously unserved county on or after January 1, 2000 and no later than December 31, 2001. The bonus payment amounts equal—

(i) For the first 12 months after a plan is offered in a previously unserved county, 5 percent of the monthly capitation rate otherwise payable under this section; and

(ii) For the subsequent 12 months, 3 percent of the monthly capitation rate otherwise payable under this section.

(2) A previously unserved county is defined as—

(i) A county in which no M+C plan has been offered;

(ii) A county in which an M+C plan or plans have been offered, but where all M+C organizations offering an M+C plan notified CMS by October 13, 1999, that they will no longer offer plans in the county as of January 1, 2000; or

(iii) A county in which an M+C plan or plans have been offered, but where all M+C organizations offering an M+C plan notified CMS by October 3, 2000, that they will no longer offer plans in the county as of January 1, 2001.

(3) A plan is considered to be offered when—

(i) The M+C organization sponsoring the plan has a contract in effect to serve beneficiaries in the previously unserved area; and

(ii) The M+C plan is open for enrollment.

[63 FR 35090, June 26, 1998; 63 FR 52613, Oct. 1, 1998, as amended at 65 FR 40325, June 29, 2000; 67 FR 13288, Mar. 22, 2002; 68 FR 50858, Aug. 22, 2003]

§422.252 Annual capitation rates.

Subject to the adjustments specified in this subpart, the annual capitation rate for a particular payment area is equal to the largest of the following:

(a) *Blended capitation rate.* The blended capitation rate is the sum of—

(1) The area-specific percentage (specified in §422.254(a)) for the year multiplied by the annual area-specific capitation rate for the payment area as determined under §422.254(e) for the year, and

(2) The national percentage (specified in §422.254(a)) for the year multiplied by the national input-price-adjusted capitation rate for the payment area as determined under §422.254(g) for the year.

(3) Multiplied by the budget neutrality adjustment factor determined under §422.254(d).

(b) *Minimum amount rate.* (1) For 1998—

(i) For the 50 States and the District of Columbia, the minimum amount rate is 12 times $367.

(ii) For all other jurisdictions the minimum amount rate is the lesser of the rate described in (b)(1)(i) or 150 percent of the capitation payment rate for 1997.

(2) For 1999, 2000, and January and February of 2001, the minimum amount rate is the minimum amount rate for the preceding year, increased by the national per capita growth percentage (specified in §422.254(b)) for the year.

(3) For March through December, 2001—

(i) The minimum amount rate for any area in a metropolitan statistical area within the 50 States and the District of Columbia with a population of more than 250,000 is $525;

(ii) For any other area within the 50 States, it is $475; or

(iii) For any area outside the 50 States and the District of Columbia, it is not more than 120 percent of the minimum amount rates for CY 2000.

(4) For 2002 and each succeeding year, the minimum amount rate is the minimum amount for the preceding year, increased by the national per capita percentage (specified in §422.252(b)) for the year.

(c) *Minimum percentage increase rate.* (1) For 1998, the minimum percentage increase rate is 102 percent of the annual capitation rate for 1997.

(2) For 1999, 2000, and January and February of 2001, the minimum percentage increase is 102 percent of the annual Medicare+Choice capitation rate for the preceding year.

(3) For March through December of 2001, the minimum percentage increase is 103 percent of the annual Medicare+Choice capitation rate for 2000.

(4) For 2002, and for each succeeding year, the minimum percentage increase is 102 percent of the annual Medicare+Choice capitation rate for the preceding year.

[63 FR 35090, June 26, 1998, as amended at 67 FR 13288, Mar. 22, 2002]

§422.254 Calculation and adjustment factors.

The following are the factors used in calculating the per capita payment rates:

(a) *Area-specific and national percentages.* For purposes of §422.252(a)(1), the area-specific percentage and the national percentage, for each year, are as follows:

	Area-specific	National
For 1998	90	10
For 1999	82	18
For 2000	74	26
For 2001	66	34
For 2002	58	42
For years after 2002	50	50

(b) *National per capita growth percentage.* For purposes of §422.252(a)(2),

(1) The national per capita growth percentage for a year is CMS's estimate of the rate of growth in per capita expenditures, reduced by the percentage points specified in paragraph (b)(2) of this section for the year. CMS may make separate estimates for aged enrollees, disabled enrollees, and enrollees who have ESRD.

(2) The percentage points that CMS uses to reduce its estimates are as follows:

(i) For 1998, 0.8 percentage points.

(ii) For years 1999 through 2001, 0.5 percentage points.

(iii) For 2002, 0.3 percentage points.

(iv) For years after 2002, 0 percentage points.

(c) *Medical education payment adjustments.* For purposes of paragraph (e)(2) the medical education payment adjustments are amounts that CMS estimates were payable to teaching hospitals during 1997 for—

(1) the indirect costs of medical education under section 1886(d)(5)(B) of the Act; and

(2) The direct costs of graduate medical education under section 1886(h) of the Act.

(d) *General budget neutrality factor.* For each year, CMS applies a budget neutrality factor to the blended capitation rates under §422.252(a) so that the estimated aggregate payments made under this part equal the estimated aggregate payments that would have been made if based entirely on area-specific capitation rates.

(e) *Annual Area-specific capitation rate* (1) *Basic rule.* Subject to the provisions of paragraphs (e)(2) and (e)(3) of this section, the annual area-specific capitation rate for a particular payment area is—

(i) For 1998, subject to paragraph (e)(4) of this section, the per capita rate determined for that area for 1997 under section 1876(a)(1)(c) of the Act, increased by the national per capita growth percentage for 1998; and

(ii) For a subsequent year, the area-specific capitation rate determined for the previous year, increased by the national per capita growth percentage for the year.

(2) *Exclusion of medical education costs.* In calculating the area-specific capitation rates, the following percentages of the amounts estimated by CMS under §422.254(c) as medical education payment adjustments to hospitals, are excluded:

For 1998	20 percent.
For 1999	40 percent.
For 2000	60 percent.
For 2001	80 percent.
For years after 2001	100 percent.

(3) *Payments under the State hospital reimbursement system.* To the extent that CMS estimates that a 1997 per capita rate reflects payments to hospitals under section 1814(b)(3) of the Act, CMS makes a payment adjustment that is comparable to the adjustment that would have been made under paragraph (e)(2) of this section if the hospitals had not been reimbursed under section 1814(b)(3) of the Act.

(4) *Areas with highly variable per capita rates.* With respect to a payment area for which the per capita rate for 1997 varies by more than 20 percent from the per capita rate for 1996, CMS may substitute for the 1997 rate a rate that is more representative of the costs of the enrollees in the area.

(f) *National standardized annual capitation rate.* The national standardized annual capitation rate is equal to—

(1) The sum, for all payment areas, of the products of—

(i) The annual area-specific capitation rate and

(ii) The average number of Medicare beneficiaries residing in the area multiplied by the average of the risk-factor weights used to adjust payments under §422.256(c);

(2) Divided by the sum, for all payment areas, of the products specified in paragraph (f)(1)(ii) of this section for all payment areas.

(g) *The input-price-adjusted annual national capitation rate*—(1) *General rule.* The input-price-adjusted annual national capitation rate for a M+C payment area for a year is equal to the sum, for all the types of Medicare services (as classified by CMS), of the product (for each service) of—

(i) The national standardized annual M+C capitation rate (determined under paragraph (f) of this section) for the year;

(ii) The proportion of such rates for the year which is attributable to such type of services; and

(iii) An index that reflects (for that year and that type of services) the relative input price of such services in the area compared to the national average input price for such services.

(2) CMS may, subject to the special rules for 1988, use indices that are used in applying or updating national payment rates for particular areas and localities.

(3) *Special rules for 1988.* In applying this paragraph for 1998—

(i) Medicare services are classified as Part A and Part B services;

(ii) The proportion attributable to Part A services is the ratio (expressed as a percentage) of the national average per capita rate of payment for Part

A services for 1997 to the national average per capita rate of payment for Part A and Part B services for that year;

(iii) The proportion attributed to part B services is 100 percent minus the ratio described in paragraph (g)(3)(ii) of this section;

(iv) For Part A services, 70 percent of the payments attributable to those services are adjusted by the index used under section 1886(d)(3)(E) of the Act to adjust payment rates for relative hospital wage levels for hospitals located in the particular payment area; and

(v) For part B services—

(A) 66 percent of payments attributable to those services are adjusted by the index of the geographic area factors under section 1848(e) of the Act used to adjust payment rates for physician services in the particular payment area; and

(B) Of the remaining 34 percent, 40 percent is adjusted by the index specified in paragraph (g)(3)(iv) of this section.

[63 FR 35090, June 26, 1998, as amended at 65 FR 40326, June 29, 2000]

§422.256 Adjustments to capitation rates and aggregate payments.

(a) *Adjustment for over or under projection of national per capita growth percentages.* (1) Beginning with rates for 1999, CMS adjusts all area-specific and national capitation rates for the previous year to reflect any differences between the projected national per capita growth percentages for that year and previous years, and the current estimates of those percentages for such years.

(2) Beginning with rates for 2000, CMS also adjusts the minimum amount rate (calculated under §422.252(b)) in the same manner.

(b) *Adjustment for national coverage determination (NCD) services and legislative changes in benefits.* If CMS determines that the cost of furnishing an NCD service or legislative change in benefits is significant, as defined in §422.109, CMS will adjust capitation rates or make other payment adjustments, to account for the cost of the service or legislative change in benefits. Until the new capitation rates are in effect, the M+C organization will be paid for the significant cost NCD service or legislative change in benefits on a fee-for-service basis as provided under §422.109(b). The Office of the Actuary in CMS will apply a new NCD adjustment factor each year that reflects significant costs of NCDs and legislative changes in benefits for coverage effective in the second prior year. The new NCD adjustment factor will be applied to the 2 percent minimum update rate described in §422.252(c).

(c) *Risk adjustment: General rule.* Capitation payments are adjusted for age, gender, institutional status, and other appropriate factors, including health status.

(d) *Risk adjustment: Health status*—(1) *Data collection.* To adjust for health status, CMS applies a risk factor based on data obtained in accordance with §422.257.

(2) *Implementation.* CMS applies the risk adjustment factor as follows:

(i) For payments beginning January 1, 2001 and ending December 31, 2003, CMS applies a risk factor that incorporates inpatient hospital encounter data. The risk factor will comprise 10 percent of the monthly payment.

(ii) For payments beginning January 1, 2000 and ending December 31, 2001 only, the risk factor comprises 100 percent of the monthly payment for individuals with a qualifying inpatient diagnosis of congestive heart failure who are enrolled in a coordinated care plan that is the only coordinated care plan offered on January 1, 2001 in the area where the individual lives.

(iii) For payments beginning January 1, 2004, and for all succeeding years, CMS applies a risk factor that incorporates inpatient hospital and ambulatory encounter data. This factor is phased in as follows:

(A) 30 percent in 2004;

(B) 50 percent in 2005;

(C) 75 percent 2006; and

(D) 100 percent in 2007 and succeeding years.

(3) *Uniform application.* Except as provided for M+C RFB plans under §422.250(a)(2)(iii), CMS applies this adjustment factor to all types of plans.

[63 FR 35090, June 26, 1998, as amended at 67 FR 13288, Mar. 22, 2002; 68 FR 50858, Aug. 22, 2003]

§ 422.257 Encounter data.

(a) *Data collection: Basic rule.* Each M+C organization must submit to CMS (in accordance with CMS instructions) all data necessary to characterize the context and purposes of each encounter between a Medicare enrollee and a provider, supplier, physician, or other practitioner.

(b) *Types of service and timing of submittal.* M+C organizations must submit data as follows:

(1) Beginning on a date determined by CMS, inpatient hospital care data for all discharges that occur on or after July 1, 1997.

(2) CMS will provide advance notice to M+C organizations to collect and submit data for services that occur on or after July 1, 1998, as follow:

(i) Physician, outpatient hospital, SNF, and HHA data beginning no earlier than October 1, 1999; and

(ii) All other data CMS deems necessary beginning no earlier than October 1, 2000.

(c) *Sources and extent of data.* (1) To the extent required by CMS, the data must account for services covered under the original Medicare program, for Medicare covered services for which Medicare is not the primary payor, or for other additional or supplemental benefits that the M+C organization may provide.

(2) The data must account separately for each provider, supplier, physician, or other practitioner that would be permitted to bill separately under the Medicare fee-for-service program, even if they participate jointly in the same encounter.

(d) *Other data requirements.* (1) M+C organizations must submit data that conform to the requirements for equivalent data for Medicare fee-for-service when appropriate, and to all relevant national standards.

(2) The data must be submitted electronically to the appropriate CMS contractor.

(3) M+C organizations must obtain the encounter data required by CMS from the provider, supplier, physician, or other practitioner that rendered the services.

(4) M+C organizations may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of complete and accurate encounter data as required by CMS. These provisions may include financial penalties for failure to submit complete data, or for failure to submit data that conform to the requirements for equivalent data for Medicare fee-for-service.

(e) *Validation of data.* M+C organizations and their providers and practitioners will be required to submit medical records for the validation of encounter data, as prescribed by CMS.

(f) *Use of data.* CMS uses the data obtained under this section to determine the risk adjustment factor that it applies to annual capitation rates under § 422.256(c). CMS may also use the data for other purposes.

(g) *Deadlines for submission of encounter data.* Risk adjustment factors for each payment year are based on encounter data submitted for services furnished during the 12 month period ending 6 months before to the payment year (for example, risk adjustment factors for CY 2000 are based on data for services furnished during the period July 1, 1998 through June 30, 1999).

(1) The annual deadline for encounter data submission is September 10 for encounter data reflecting services furnished during the 12 month period ending the prior June 30 (for example, the deadline for submission of data for the period July 1, 1998 through June 30, 1999 is September 10, 1999).

(2) CMS allows a reconciliation process to account for late data submissions. CMS continues to accept encounter data submitted after the September 10 deadline until June 30 of the payment year (for example, until June 30, 2000 for data from the period July 1, 1998 through June 30, 1999). After the payment year is completed, CMS recalculates the risk factors for affected individuals to determine if adjustments to payments are necessary.

[63 FR 35090, June 26, 1998, as amended at 65 FR 40326, June 29, 2000]

§ 422.258 Announcement of annual capitation rates and methodology changes.

(a) *Capitation rates.* (1) No later than March 1 of each year, CMS announces

to M+C organizations and other interested parties the capitation rates for the following calendar year.

(2) CMS includes in the announcement a description of the risk and other factors and explains the methodology in sufficient detail to enable M+C organizations to compute monthly adjusted capitation rates for individuals in each of its payment areas.

(b) *Advance notice of changes in methodology.* (1) No later than January 15 of each year, CMS notifies M+C organizations of changes it proposes to make in the factors and the methodology it used in the previous determination of capitation rates.

(2) The M+C organizations have 15 days to comment on the proposed changes.

§ 422.262 Special rules for beneficiaries enrolled in M+C MSA plans.

(a) *Establishment and designation of medical savings account (MSA).* A beneficiary who elects coverage under an M+C MSA plan—

(1) Must establish an M+C MSA with a trustee that meets the requirements of paragraph (b) of this section; and

(2) If he or she has more than one M+C MSA, designate the particular account to which payments under the M+C MSA plan are to be made.

(b) *Requirements for MSA trustees.* An entity that acts as a trustee for an M+C MSA must—

(1) Register with CMS;

(2) Certify that it is a licensed bank, insurance company, or other entity qualified, under sections 408(a)(2) or 408(h) of the IRS Code, to act as a trustee of individual retirement accounts;

(3) Agree to comply with the M+C MSA provisions of section 138 of the IRS Code of 1986; and

(4) Provide any other information that CMS may require.

(c) *Deposit in the M+C MSA.* (1) The payment is calculated as follows:

(i) The monthly M+C MSA premium is compared with 1/12 of the annual capitation rate for the area determined under § 422.252.

(ii) If the monthly M+C MSA premium is less than 1/12 of the annual capitation rate, the difference is the amount to be deposited in the M+C MSA for each month for which the beneficiary is enrolled in the MSA plan.

(2) CMS deposits the full amount to which a beneficiary is entitled under paragraph (c)(1)(ii) of this section for the calendar year, beginning with the month in which M+C MSA coverage begins.

(3) If the beneficiary's coverage under the M+C MSA plan ends before the end of the calendar year, CMS recovers the amount that corresponds to the remaining months of that year.

§ 422.264 Special rules for coverage that begins or ends during an inpatient hospital stay.

(a) *Applicability.* This section applies to inpatient services in a "subsection (d) hospital" as defined in section 1886(d)(1)(B) of the Act.

(b) *Coverage that begins during an inpatient hospital stay.* If coverage under an M+C plan offered by an M+C organization begins while the beneficiary is an inpatient in a subsection (d) hospital—

(1) Payment for inpatient services until the date of the beneficiary's discharge is made by the previous M+C organization or original Medicare, as appropriate.

(2) The M+C organization offering the newly-elected M+C plan is not responsible for the inpatient services until the date after the beneficiary's discharge; and

(3) The M+C organization offering the newly-elected M+C plan is paid the full amount otherwise payable under this subpart.

(c) *Coverage that ends during an inpatient hospital stay.* If coverage under an M+C plan offered by an M+C organization ends while the beneficiary is an inpatient in a subsection (d) hospital—

(1) The M+C organization is responsible for the inpatient services until the date of the beneficiary's discharge;

(2) Payment for those services during the remainder of the stay is not made by original Medicare or by any succeeding M+C organization offering a newly-elected M+C plan; and

(3) The M+C organization that no longer provides coverage receives no payment for the beneficiary for the period after coverage ends.

§ 422.266 Special rules for hospice care.

(a) *Information.* An M+C organization that has a contract under subpart K of this part must inform each Medicare enrollee eligible to select hospice care under §418.24 of this chapter about the availability of hospice care (in a manner that objectively presents all available hospice providers, including a statement of any ownership interest in a hospice held by the M+C organization or a related entity) if—

(1) A Medicare hospice program is located within the plan's service area; or

(2) It is common practice to refer patients to hospice programs outside that area.

(b) *Enrollment status.* Unless the enrollee disenrolls from the M+C plan, a beneficiary electing hospice continues his or her enrollment in the M+C plan and is entitled to receive, through the M+C plan, any benefits other than those that are the responsibility of the Medicare hospice.

(c) *Payment.* (1) No payment is made to an M+C organization on behalf of a Medicare enrollee who has elected hospice care under §418.24 of this chapter except for the portion of the payment applicable to the additional benefits described in §422.312. This no-payment rule is effective from the first day of the month following the month of election to receive hospice care, until the first day of the month following the month in which the election is terminated.

(2) During the time the hospice election is in effect, CMS's monthly capitation payment to the M+C organization is reduced to an amount equal to the adjusted excess amount determined under §422.312. In addition, CMS pays through the original Medicare program (subject to the usual rules of payment)—

(i) The hospice program for hospice care furnished to the Medicare enrollee; and

(ii) The M+C organization, provider, or supplier for other Medicare-covered services to the enrollee.

[63 FR 35085, June 26, 1998, as amended at 68 FR 50858, Aug. 22, 2003]

§ 422.268 Source of payment and effect of election of the M+C plan election on payment.

(a) *Source of payments.* Payments under this subpart, to M+C organizations or M+C MSAs, are made from the Federal Hospital Insurance Trust Fund or the Supplementary Medical Insurance Trust Fund. CMS determines the proportions to reflect the relative weight that benefits under Part A, and benefits under Part B represents of the actuarial value of the total benefits under title XVIII of the Act.

(b) *Payments to the M+C organization.* Subject to §§412.105(g) and 413.86(d) of this chapter and §§422.109, 422.264, and 422.266, CMS's payments under a contract with an M+C organization (described in §422.250) with respect to an individual electing an M+C plan offered by the organization are instead of the amounts which (in the absence of the contract) would otherwise be payable under original Medicare for items and services furnished to the individual.

(c) *Only the M+C organization entitled to payment.* Subject to §422.262, 422.264, 422.266, and 422.520 of this part and sections 1886(d)(11) and 1886(h)(3)(D) of the Act, only the M+C organization is entitled to receive payment from CMS under title XVIII of the Act for items and services furnished to the individual.

[63 FR 35090, June 26, 1998; 63 FR 52613, Oct. 1, 1998]

§ 422.270 Payments to M+C organizations for graduate medical education costs.

(a) Effective January 1, 1999, Medicare+Choice organizations may receive direct graduate medical education payments for the time that residents spend in nonhospital provider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs.

(b) Medicare+Choice organizations may receive direct graduate medical education payments if all of the following conditions are met:

(1) The resident spends his or her time assigned to patient care activities.

(2) The Medicare+Choice organization incurs "all or substantially all" of the costs for the training program in

the nonhospital setting as defined in §413.86(b) of this subchapter.

(3) There is a written agreement between the Medicare+Choice organization and the nonhospital site that indicates the Medicare+Choice organization will incur the costs of the resident's salary and fringe benefits and provide reasonable compensation to the nonhospital site for teaching activities.

(c) A Medicare+Choice organization's allowable direct graduate medical education costs, subject to the redistribution and community support principles specified in §413.85(c) of this subchapter, consist of—

(1) Residents' salaries and fringe benefits (including travel and lodging where applicable); and

(2) Reasonable compensation to the nonhospital site for teaching activities related to the training of medical residents.

(d) The direct graduate medical education payment is equal to the product of—

(1) The lower of—

(i) The Medicare+Choice organization's allowable costs per resident as defined in paragraph (c) of this section; or

(ii) The national average per resident amount; and

(2) Medicare's share, which is equal to the ratio of the number of Medicare beneficiaries enrolled to the total number of individuals enrolled in the Medicare+Choice organization.

(e) Direct graduate medical education payments made to Medicare+Choice organizations under this section are made from the Federal Supplementary Medical Insurance Trust Fund.

[66 FR 3376, Jan. 12, 2001]

Subpart G—Premiums and Cost-Sharing

SOURCE: 63 FR 35093, June 26, 1998, unless otherwise noted.

§422.300 Basis and scope.

(a) *General.* This subpart is based on section 1854 of the Act. It sets forth the requirements and limitations for payments by and on behalf of Medicare beneficiaries who elect an M+C plan.

(b) *Transition period.* For contract periods beginning before January 1, 2002, CMS applies the following special rules.

(1) M+C organizations may, with CMS's agreement, modify an M+C plan offered prior to January 1, 2002 by—

(i) Adding benefits at no additional cost to the M+C plan enrollee; and

(ii) Lowering the premiums approved through the ACR process;

(iii) Lowering other cost-sharing amounts approved through the ACR process.

(2) For contracts beginning on a date other than January 1 (according to §422.504(d)), M+C organizations may submit ACRs on a date other than July 1 approved by CMS.

[63 FR 35093, June 26, 1998, asa amended at 65 FR 40326, June 29, 2000]

§422.302 Terminology.

As used in this subpart, unless specified otherwise—

Additional revenues are revenues collected or expected to be collected from charges for M+C plans offered by an M+C organization in excess of costs actually incurred or expected to be incurred. Additional revenues would include such things as revenues in excess of expenses of an M+C plan, profits, contribution to surplus, risk margins, contributions to risk reserves, assessments by a related entity that do not represent a direct medical or related administrative cost, and any other premium component not reflected in direct medical care costs and administrative costs.

APR stands for the M+C plan's average per capita rates of payment. The APR is the average amount the M+C organization estimates CMS will pay (without any needed offsets or reductions, such as, those required by §422.250(a)(2)(ii) for M+C MSA plan enrollees) for the period covered by the ACR for all of the Medicare beneficiaries electing the M+C plan.

M+C monthly basic beneficiary premium means, with respect to an M+C coordinated care plan, the amount authorized to be charged under §422.308(a)(1) for

the plan, or, with respect to a M+C private fee-for-service plan, the amount filed under § 422.306(d)(1).

M+C monthly supplemental beneficiary premium means, with respect to an M+C coordinated care plan, the amount authorized to be charged under § 422.308(a)(2) for the M+C plan, or, with respect to an MSA or an M+C private fee-for-service plan, the amount filed under § 422.306(c)(2) or § 422.306(d)(2).

M+C monthly MSA premium means, with respect to an M+C plan, the amount of such premium filed under § 422.306(c)(1).

§ 422.304 Rules governing premiums and cost-sharing.

(a) *Monthly premiums.* The monthly premium charged to the beneficiary is—

(1) For an individual enrolled in an M+C plan (other than an M+C MSA plan) offered by an M+C organization, the sum of the M+C monthly basic beneficiary premium plus the M+C monthly supplemental beneficiary premium (if any); or

(2) For an individual enrolled in an M+C MSA plan offered by an M+C organization, the M+C monthly supplemental beneficiary premium (if any).

(b) *Uniformity.*—(1) *General rule.* The M+C monthly basic beneficiary premium, the M+C monthly supplemental beneficiary premiums, and the M+C monthly MSA premium of an M+C organization may not vary among individuals enrolled in an M+C plan (or segment of the plan as provided under paragraph (b)(2) of this section). In addition, the M+C organization may not vary the level of cost-sharing charged for basic benefits or supplemental benefits (if any), among individuals enrolled in an M+C plan (or segment of the plan as provided under paragraph (b)(2) of this section).

(2) *Segmented service area option.* An M+C organization may apply the uniformity requirements in paragraph (b)(1) of this section to segments of an M+C plan service area (rather than to the entire service area) as long as any such segment is composed of one or more M+C payment areas, and the information specified under § 422.306 is submitted separately, as provided in that section, for each such segment.

(c) *Timing of payments.* The M+C organization must permit payments of M+C monthly basic and supplemental beneficiary premium on a monthly basis and may not terminate coverage for failure to make timely payments except as provided in § 422.74(b)(1).

(d) *Monetary inducements prohibited.* An M+C organization may not provide for cash or other monetary rebates as an inducement for enrollment or for any other reason or purpose.

[63 FR 35093, June 26, 1998, asa amended at 65 FR 40326, June 29, 2000]

§ 422.306 Submission of proposed premiums and related information.

(a) *General rule.* (1) Not later than July 1 of each year, each M+C organization and any organization intending to contract as an M+C organization in the subsequent year must submit to CMS, in the manner and form prescribed by CMS, for each M+C plan (or service area segment, under § 422.304(b)(2)) it intends to offer in the following year—

(i) The information specified in paragraph (b), (c), or paragraph (d) of this section for the type of M+C plan involved; and

(ii) The service area and enrollment capacity (if any).

(2) If the submission is not complete, timely, or accurate, CMS has the authority to impose sanctions under subpart O of this part or may choose not to renew the contract.

(b) *Information required for coordinated care plans*—(1) *Basic benefits.* For basic benefits, the following information is required:

(i) The ACR as specified in § 422.310.

(ii) The M+C monthly basic beneficiary premium.

(iii) A description of cost-sharing to be imposed under the plan, and its actuarial value.

(iv) A description of any additional benefits to be provided pursuant to § 422.312 and the actuarial value determined for those benefits.

(v) Amounts collected in the previous contract period for basic benefits.

(2) *Supplemental benefits.* For supplemental benefits, the following information is required:

(i) The ACR.

(ii) The M+C monthly supplemental beneficiary premium.

(iii) A description of supplemental benefits being offered, the cost sharing to be imposed, and their actuarial value.

(iv) Amounts collected in the previous contract period for supplemental benefits.

(c) *Information required for MSA plans.* (1) The monthly MSA premium for basic benefits.

(2) The M+C monthly supplementary beneficiary premium for supplemental benefits.

(3) A description of all benefits offered under the M+C MSA plan.

(4) The amount of the deductible imposed under the plan.

(5) Amounts collected in the previous contract period for supplemental benefits.

(d) *Information required for M+C private fee-for-service plans.* (1) The information specified under paragraph (b)(1) of this section.

(2) The amount of the M+C monthly supplemental beneficiary premium.

(3) A description of all benefits offered under the plan.

(4) Amounts collected in the previous contract period for basic and supplemental benefits.

(e) *CMS review*—(1) *Basic rule.* Except as specified in paragraph (e)(2) of this section, CMS reviews and approves or disapproves the information submitted under this section.

(2) *Exception.* CMS does not review or approve or disapprove the following information:

(i) Any amounts submitted with respect to M+C MSA plans.

(ii) The M+C monthly basic and supplementary beneficiary premiums for M+C private fee-for-service plans.

[63 FR 35093, June 26, 1998, as amended at 65 FR 40326, June 29, 2000]

§422.308 Limits on premiums and cost sharing amounts.

(a) *Rules for coordinated care plans.* (1) For basic benefits, the M+C monthly basic beneficiary premium (multiplied by 12) charged, plus the actuarial value of the cost-sharing applicable, on average, to beneficiaries enrolled under this part may not exceed the annual actuarial value of the deductibles and coinsurance that would be applicable, on average, to beneficiaries entitled to Medicare Part A and enrolled in Medicare Part B if they were not enrollees of an M+C organization as determined in the ACR under §422.310. For those M+C plan enrollees that are enrolled in Medicare Part B only, the M+C monthly basic beneficiary premium (multiplied by 12) charged, plus the actuarial value of the deductibles, coinsurance and copayments applicable, on average, to those beneficiaries enrolled under this part may not exceed the annual actuarial value of the deductibles and coinsurance that would be applicable, on average, to beneficiaries enrolled in Medicare Part B if they were not enrollees of an M+C organization as determined in the ACR under §422.310.

(2) For supplemental benefits, the M+C monthly supplemental beneficiary premium (multiplied by 12) charged, plus the actuarial value of its cost-sharing, may not exceed the amounts approved in the ACR for those benefits, as determined under §422.310 on an annual basis.

(3) *Coverage of Part A services for Part B-only Medicare enrollees.* If an M+C organization furnishes coverage of Medicare Part A-type services to a Medicare enrollee entitled to Part B only, the M+C plan's premium plus the actuarial value of its cost-sharing for these services may not exceed the lesser of—

(i) The APR that is payable for these services for those beneficiaries entitled to Part A plus the actuarial value of Medicare deductibles and Coinsurance for the services;

(ii) or the ACR for such services.

(b) *Rule for M+C private fee-for-service plans.* (1) The average actuarial value of the cost-sharing for basic benefits may not exceed the actuarial value of the cost-sharing that would apply, on average, to beneficiaries entitled to Medicare Part A and enrolled in Medicare Part B if they were not enrolled in an M+C plan as determined in the ACR under §422.310.

(2) For supplemental benefits, the actuarial value of its cost-sharing may not exceed the amounts approved in the ACR for those benefits, as determined under §422.310 on an annual basis.

(c) *Special rules for determination of actuarial value.* If CMS determines that adequate data are not available to determine actuarial value under paragraph (a) or (b) of this section, CMS may make the determination with respect to all M+C eligible individuals in the same geographic area or State or in the United States, or on the basis of other appropriate data.

[63 FR 35093, June 26, 1998; 63 FR 52614, Oct. 1, 1998]

§ 422.309 Incorrect collections of premiums and cost-sharing.

(a) *Definitions.* As used in this section—

(1) *Amounts incorrectly collected*

(i) Means amounts that:

(A) Exceed the limits imposed by § 422.308;

(B) In the case of a M+C private fee-for-service plan, exceed the M+C monthly basic beneficiary premium or the M+C monthly supplemental premium submitted under § 422.306; and

(C) In the case of a M+C MSA plan, exceed the M+C monthly supplemental premium submitted under § 422.306 and the deductible for basic benefits; and

(ii) Includes amounts collected from an enrollee who was believed not entitled to Medicare benefits but was later found to be entitled.

(2) *Other amounts due* are amounts due for services that were—

(i) Emergency, urgently needed services, or other services obtained outside the M+C plan; or

(ii) Initially denied but, upon appeal, found to be services the enrollee was entitled to have furnished by the M+C organization.

(b) *Basic commitments.* An M+C organization must agree to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and to pay any other amounts due the enrollees or others on their behalf.

(c) *Refund methods*—(1) *Lump-sum payment.* The M+C organization must use lump-sum payments for the following:

(i) Amounts incorrectly collected that were not collected as premiums.

(ii) Other amounts due.

(iii) All amounts due if the M+C organization is going out of business or terminating its M+C contract for an M+C plan(s).

(2) *Premium adjustment or lump-sum payment, or both.* If the amounts incorrectly collected were in the form of premiums, or included premiums as well as other charges, the M+C organization may refund by adjustment of future premiums or by a combination of premium adjustment and lump-sum payments.

(3) *Refund when enrollee has died or cannot be located.* If an enrollee has died or cannot be located after reasonable effort, the M+C organization must make the refund in accordance with State law.

(d) *Reduction by CMS.* If the M+C organization does not make the refund required under this section by the end of the contract period following the contract period during which an amount was determined to be due an enrollee, CMS reduces the premium the M+C organization is allowed to charge an M+C plan enrollee by the amounts incorrectly collected or otherwise due. In addition, the M+C organization would be subject to sanction under subpart O for failure to refund amounts incorrectly collected from M+C plan enrollees.

§ 422.310 Adjusted community rate (ACR) approval process.

(a) *General rule.* (1) Except with respect to M+C MSA plans, each M+C organization must compute a separate ACR for each M+C coordinated care or private fee-for-service plan offered to Medicare beneficiaries. In computing the ACR, the M+C organization calculates an initial rate (for years after 1999, using the methods described in paragraph (b), for 1999, under § 417.594(b)) that represents the "commercial premium" the M+C organization would charge its general non-Medicare eligible enrollment population for the basic benefits, and any mandatory supplemental benefits covered under the M+C plan. The M+C organization should also calculate a separate initial rate (using the same approach) for each optional supplemental benefit package it offers under an M+C plan. For years after 1999 the M+C organization then either adjusts that

rate by the factors specified in paragraph (c) of this section or requests that CMS adjust the rate in accordance with the procedures specified in paragraph (c)(6) of this section. For 1999, adjustments are made under section 417.594(c). All data submitted as part of the ACR process is subject to audit by CMS or any person or organization designated by CMS.

(2) To calculate the adjusted excess described in section 422.312, the M+C organization or CMS further reduces the rate for Medicare-covered services by the actuarial value of applicable Medicare coinsurance and deductibles.

(3) Separate ACRs must be calculated for Part A and Part B enrollees and Part B-only enrollees for each M+C plan offered, and for each optional supplemental benefit option.

(4) In calculating its initial rate, the M+C organization must identify and take into account anticipated revenue collectible from other payers for those services for which Medicare is not the primary payer as described in §422.108.

(5) Except as provided in paragraph (a)(6) of this section, the M+C organization must have an adequate accounting system that is accrual based and uses generally-accepted accounting principles to develop its ACR.

(6) For M+C organizations that are part of a government entity that uses a cash basis of accounting, ACR cost data developed on this basis is acceptable. However, only depreciation on capital assets, rather than the expenditure for the asset, is acceptable.

(b) *Initial rate calculation for years after 1999.* (1) The M+C organization's initial rate for each M+C plan is calculated on a 12-month basis for non-Medicare enrollees, using either, at the M+C organization's election—

(i) A community rating system (as defined in section 1308(8) of the PHS Act, other than subparagraph (C)); or

(ii) A system, approved by CMS, under which the M+C organization develops an aggregate premium for each M+C plan for all enrollees of that M+C plan that is weighted by the size of the various enrolled groups and individuals that compose the M+C organization's enrollment in that M+C plan. For purposes of this section, enrolled groups are defined as employee groups or other bodies of subscribers (including individual subscribers) that enroll in the M+C plan on a premium basis.

(2) Regardless of which method the M+C organization uses to calculate its initial rate, the initial rate must be equal to the premium the M+C organization would charge its non-Medicare enrollees on a yearly basis for services included in the M+C plan.

(3) Except as provided in paragraph (b)(4) of this section, the M+C organization must identify in its initial rate calculation for an M+C plan, the following components whose rates must be consistent with rates used by the M+C organization in calculating premiums for non-Medicare enrollees:

(i) Direct medical care.

(ii) Administration.

(iii) Additional Revenues.

(iv) Enrollee cost sharing (for example, deductibles, coinsurance, or copayments) for Medicare-covered services and for additional and supplemental benefits.

(4) An M+C organization that does not usually separate its premium components as described in paragraph (b)(3) of this section may calculate its initial rate with the methods it uses for its other enrolled groups if the M+C organization provides CMS with the documentation necessary to support any adjustments the M+C organization makes to the initial rate in accordance with paragraph (c)(5) of this section.

(5) The initial rate calculation must not carry forward any losses experienced by the M+C organization during prior contract periods. The M+C organization must submit supporting documentation to assure CMS that ACR values do not include past losses but only premiums for covered services, additional services, and supplemental benefits for the upcoming 12-month period.

(c) *Adjustment factors for years after 1999.* Adjustment factors are designed to adjust on a component basis the initial rate calculated under paragraph (b) of this section to reflect differences in utilization characteristics of the M+C organization's Medicare enrollees electing an M+C plan using a relative cost ratio. Adjustment factors are as follows:

(1) *Direct medical care.* The relative cost ratio for direct medical care for an M+an is determined by comparing the direct medical care costs actually incurred on an accrual basis during the most recently ended calendar year prior to submission of the ACR for Medicare enrollees that elected the M+C plan to the direct medical care costs of non-Medicare enrollees incurred over the same period. The non-Medicare enrollees included in this computation must be consistent with the non-Medicare enrollees included in the initial rate computation.

(2) *Administration.* The relative cost ratio for Administration for an M+C plan is determined by comparing the administrative costs actually incurred on an accrual basis during the most recently ended calendar year prior to submission of the ACR for Medicare enrollees that elected the M+C plan to the administrative costs of non-Medicare enrollees incurred over the same period. The non-Medicare enrollees included in this computation must be consistent with the non-Medicare enrollees included in the initial rate computation.

(3) *Additional revenues.* The relative cost ratio for total revenues for an M+C plan is determined by comparing the total revenues charged on an accrual basis during the most recently ended calendar year prior to submission of the ACR for Medicare enrollees (including payments from CMS without any needed offsets or reductions, such as, those required by §422.250(a)(2)(i)(B) for ESRD enrollees) that elected the M+C plan to the total revenues charged for non-Medicare enrollees over the same period. The non-Medicare enrollees included in this computation must be consistent with the non-Medicare enrollees included in the initial rate computation. When the relative cost ratio for total revenues is applied to the total initial rate, the value of additional revenues is the remaining value after removing the value of direct medical costs (as adjusted by paragraph (c)(1) of this section) and the value of Administration (as adjusted by paragraph (c)(2) of this section).

(4) *Additional adjustments.* Additional adjustments may be necessary if the M+C organization, with agreement of CMS, determines that the adjustment of the initial rate by the relative cost ratios does not represent an accurate ACR value of the initial rate component. In addition, adjustments will be allowed that are designed to reduce ACR values to equal the actuarial value of the M+C plan charge structure.

(5) *Supporting documentation.* All adjustments made by the M+C organization must be accompanied by adequate supporting data. If an M+C organization does not have sufficient enrollment experience to develop this data, it may, during its initial contract period use reasonable estimates acceptable to CMS to establish its ACR values.

(6) *Adjustment by CMS.* If it is determined that the M+C organization does not have adequate data to adjust the initial rate calculated under paragraph (b) of this section to reflect the utilization characteristics of Medicare enrollees, CMS adjusts the initial rate. CMS adjusts the rate on the basis of differences in the utilization characteristics of—

(i) Medicare and non-Medicare enrollees in other M+C plans; or

(ii) Medicare beneficiaries in the M+C organization's area, State, or the United States who are eligible to elect an M+C plan and other individuals in that same area, State, or the United States.

(d) *Special rules for certain organizations.* An M+C organization that does not have non-Medicare enrollees or sufficient Medicare enrollment experience to adequately calculate ACR values may calculate its ACR using estimates described in paragraphs (d)(1) and (d)(2) of this section as an additional adjustment described in paragraph (c)(4) of this section.

(1) The M+C organization may use an estimate of the ACR value for the direct medical and administrative components of a service or services offered using generally-accepted accounting principles.

(2) The M+C organization may use an estimate of the ACR value for the additional revenue component of a service or services offered based on the lesser of (if the information is available)—

(i) The average of additional revenues received through risk payments for health services contracted to be furnished to an enrolled population of other organizations;

(ii) The average of additional revenues received for health services furnished; or

(iii) A reasonable estimate of additional revenues of other M+C organizations in the general marketplace.

(e) *Adjustment by CMS.* If CMS finds that there is insufficient enrollment experience to determine the APR or ACR for a M+C plan at the beginning of a contract period, CMS may—

(1) Determine the APR based on the enrollment experience of other M+C organizations;

(2) Determine ACR using data in the general commercial marketplace; or

(3) Determine either or both rates using the best available information, which may include enrollment experience of other M+C organizations and section 1876 risk contractors.

(f) *CMS review.* (1) The M+C organization's methodology and computation of its ACR are subject to review and approval by CMS. When the M+C organization submits the ACR computation, it must include adequate supporting data. Except as provided in §422.306(e)(2), CMS authorizes the M+C organization to collect premiums and other cost sharing amounts described in §422.306 that are equal to the amounts calculated in the ACR.

(2) If the M+C organization is dissatisfied with an CMS determination that the M+C organization's computation is not acceptable, the M+C organization may within 2 weeks after the date of receipt of notification of this determination, file a request for a hearing with CMS. The request must state why the M+C organization believes the determination is incorrect and must be accompanied by any supporting evidence the M+C organization wishes to submit. The hearing is conducted by a hearing officer designated by CMS under the hearing procedures described in subpart N.

[63 FR 35093, June 26, 1998; 63 FR 52614, Oct. 1, 1998, as amended at 65 FR 40326, June 29, 2000]

§422.312 Requirement for additional benefits.

(a) *Definitions.* As used in this section—

(1) *Excess amount* is the amount by which the APR exceeds the actuarial value of the Medicare covered services required under §422.101(a), as determined on the basis of the ACR determined under §422.310, as reduced for the actuarial value of the cost-sharing under Medicare Parts A and B. A separate excess amount must be determined for Part B-only enrollees.

(2) *Adjusted excess amount* is the excess amount minus any amount withheld and reserved for the organization in a stabilization fund, as provided in paragraph (c) of this section.

(b) *Requirement for additional benefits.* If there is an adjusted excess amount for the plan it offers, the M+C organization must—

(1) Provide additional benefits with an actuarial value (less the actuarial value of any cost-sharing associated with the benefit) which CMS determines is at least equal to the adjusted excess amount; and

(2) Provide those benefits uniformly for all Medicare enrollees electing the plan.

(c) *Stabilization fund.* (1) An M+C organization may request for part of an excess amount to be withheld and reserved, for a specified number of contract periods, in the Federal Hospital Insurance Trust Fund, or the Federal Supplementary Insurance Trust Fund in the proportions that CMS determines to be appropriate.

(2) The reserved funds are to be used to stabilize and prevent undue fluctuations in the additional benefits that are required under this section and are provided during subsequent contract periods.

(3) Any amounts not provided as additional benefits during the period specified by the M+C organization for which the stabilization fund is established, reverts for the use of the trust funds.

(4) *Establishment of a stabilization fund.* An M+C organization's request to have monies withheld in a stabilization fund for a specific M+C plan must be made when the M+C organization notifies CMS under §422.306 of its proposed

premiums, other cost-sharing amounts, and related information in preparation for its next contract period.

(i) *Limit per contract period.* Except as provided in paragraph (c)(4)(iii) of this section, CMS does not withhold in a stabilization fund more than 15 percent of the excess amount for a given contract period.

(ii) *Cumulative limit.* If CMS has established a stabilization fund for an M+C plan, it does not approve a request for withholding made by that M+C organization for a subsequent contract period that would cause the total value of the stabilization fund to exceed 25 percent of the excess amount applicable to the M+C plan for that subsequent contract period.

(iii) *Exception.* CMS may grant an exception to the limit described in paragraph (c)(3)(i) of this section if the M+C organization can demonstrate to CMS's satisfaction that the value of the additional benefits it provides to its Medicare enrollees electing this M+C plan fluctuates substantially in excess of 15 percent from one contract period to another.

(iv) *Interest.* The amounts withheld in a stabilization fund are accounted for by CMS in accounts for which interest does not accrue to the M+C organization.

(5) *Withdrawal from a stabilization fund.* An M+C organization's request to make a withdrawal from the stabilization fund established for an M+C plan to be used during a contract period must be made when the M+C organization notifies CMS under §422.306 of its proposed premiums, cost-sharing amounts, and related information in preparation for its next contract period.

(i) *Notification requirements.* An M+C organization must—

(A) Indicate how it intends to use the withdrawn amounts;

(B) Justify the need for the withdrawal in terms of stabilizing the additional benefits it provides to Medicare enrollees;

(C) Document the M+C plan's experience with fluctuations of revenue requirements relative to the additional benefits it provides to Medicare enrollees; and

(D) Document its experience during the contract period previous to the one for which it requests withdrawal to ensure that the M+C organization will not be using the withdrawn amounts to refinance losses suffered during that previous contract period.

(ii) *Criteria for CMS approval.* CMS approves a request for a withdrawal from a benefit stabilization fund for use during the next contract period only if—

(A) The average of the APR for the M+C plan's next contract period of the M+C plan is less than that of the previous contract period;

(B) The M+C plan's ACR for the next contract period is significantly higher than that of the previous contract period;

(C) The M+C plan's revenue requirements for the next contract period for providing the additional benefits it provided during the previous contract period is significantly higher than the requirements for that previous period; or

(D) The ACR for the next contract period results in additional benefits that are significantly less in total value than that of the previous contract period.

(iii) *Basis for denial.* CMS does not approve a request for a withdrawal from a stabilization fund if the withdrawal would allow the M+C organization to refinance prior contract period losses or to avoid losses in the upcoming contract period.

(iv) *Form of payment.* Payment of monies withdrawn from a stabilization fund is made, in equal parts, as an additional amount to the monthly advance payment made to the M+C organization for Medicare beneficiaries electing the M+C plan during the period of the contract.

(d) *Reduction in payments.* As of January 1, 2003, as a part of providing additional benefits under paragraph (b) of this section, if there is an adjusted excess amount for the plan it offers, the M+C organization—

(1) May elect to receive a reduction (not to exceed 125 percent of the standard Part B premium amount) in its payments under §422.250(a)(1), 80 percent of which will be applied to reduce the Part B premiums of its Medicare enrollees; and

(2) Must apply the reduction uniformly to all similarly situated enrollees of the M+C plan.

(e) *Construction.* Nothing in this section may be construed as preventing an M+C organization from providing supplemental benefits in addition to those required under this section and from imposing a premium for those supplemental benefits.

[63 FR 35093, June 26, 1998, as amended at 65 FR 40326, June 29, 2000; 68 FR 50858, Aug. 22, 2003]

Subpart H—Provider-Sponsored Organizations

EDITORIAL NOTE: Nomenclature changes to subpart H appear at 63 FR 35098, 35099, June 26, 1998.

§422.350 Basis, scope, and definitions.

(a) *Basis and scope.* This subpart is based on sections 1851 and 1855 of the Act which, in part,—

(1) Authorize provider sponsored organizations, (PSOs), to contract as a M+C plan;

(2) Require that a PSO meet certain qualifying requirements; and

(3) Provide for waiver of State licensure for PSOs under specified conditions.

(b) *Definitions.* As used in this subpart (unless otherwise specified)—

Capitation payment means a fixed per enrollee per month amount paid for contracted services without regard to the type, cost, or frequency of services furnished.

Cash equivalent means those assets excluding accounts receivable that can be exchanged on an equivalent basis as cash, or converted into cash within 90 days from their presentation for exchange.

Control means that an individual, group of individuals, or entity has the power, directly or indirectly, to direct or influence significantly the actions or policies of an organization or institution.

Current ratio means total current assets divided by total current liabilities.

Deferred acquisition costs are those costs incurred in starting or purchasing a business. These costs are capitalized as intangible assets and carried on the balance sheet as deferred charges since they benefit the business for periods after the period in which the costs were incurred.

Engaged in the delivery of health care services means—

(1) For an individual, that the individual directly furnishes health care services, or

(2) For an entity, that the entity is organized and operated primarily for the purpose of furnishing health care services directly or through its provider members or entities.

Generally accepted accounting principles (GAAP) means broad rules adopted by the accounting profession as guides in measuring, recording, and reporting the financial affairs and activities of a business to its owners, creditors and other interested parties.

Guarantor means an entity that—

(1) Has been approved by CMS as meeting the requirements to be a guarantor; and

(2) Obligates its resources to a PSO to enable the PSO to meet the solvency requirements required to contract with CMS as an M+C organization.

Health care delivery assets (HCDAs) means any tangible assets that are part of a PSO's operation, including hospitals and other medical facilities and their ancillary equipment, and such property as may be reasonably required for the PSO's principal office or for such other purposes as the PSO may need for transacting its business.

Insolvency means a condition in which the liabilities of the debtor exceed the fair valuation of its assets.

Net worth means the excess of total assets over total liabilities, excluding fully subordinated debt or subordinated liabilities.

Provider-sponsored organization (PSO) means a public or private entity that—

(1) Is established or organized, and operated, by a provider or group of affiliated providers;

(2) Provides a substantial proportion (as defined in §422.352) of the health care services under the M+C contract directly through the provider or affiliated group of providers; and

(3) When it is a group, is composed of affiliated providers who—

(i) Share, directly or indirectly, substantial financial risk, as determined under §422.356, for the provision of

services that are the obligation of the PSO under the M+C contract; and

(ii) Have at least a majority financial interest in the PSO.

Qualified actuary means a member in good standing of the American Academy of Actuaries or a person recognized by the Academy as qualified for membership, or a person who has otherwise demonstrated competency in the field of actuarial determination and is satisfactory to CMS.

Statutory accounting practices means those accounting principles or practices prescribed or permitted by the domiciliary State insurance department in the State that PSO operates.

Subordinated debt means an obligation that is owed by an organization, that the creditor of the obligation, by law, agreement, or otherwise, has a lower repayment rank in the hierarchy of creditors than another creditor. The creditor would be entitled to repayment only after all higher ranking creditors' claims have been satisfied. A debt is fully subordinated if it has a lower repayment rank than all other classes of creditors.

Subordinated liability means claims liabilities otherwise due to providers that are retained by the PSO to meet net worth requirements and are fully subordinated to all other creditors.

Uncovered expenditures means those expenditures for health care services that are the obligation of an organization, for which an enrollee may also be liable in the event of the organization's insolvency and for which no alternative arrangements have been made that are acceptable to CMS. They include expenditures for health care services for which the organization is at risk, such as out-of-area services, referral services and hospital services. However, they do not include expenditures for services when a provider has agreed not to bill the enrollee.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 25376, May 7, 1998; 63 FR 35098, June 26, 1998]

§ 422.352 Basic requirements.

(a) *General rule.* An organization is considered a PSO for purposes of a M+C contract if the organization—

(1) Has obtained a waiver of State licensure as provided for under § 422.370;

(2) Meets the definition of a PSO set forth in § 422.350 and other applicable requirements of this subpart; and

(3) Is effectively controlled by the provider or, in the case of a group, by one or more of the affiliated providers that established and operate the PSO.

(b) *Provision of services.* A PSO must demonstrate to CMS's satisfaction that it is capable of delivering to Medicare enrollees the range of services required under a contract with CMS. Each PSO must deliver a substantial proportion of those services directly through the provider or the affiliated providers responsible for operating the PSO. Substantial proportion means—

(1) For a non-rural PSO, not less than 70% of Medicare services covered under the contract.

(2) For a rural PSO, not less than 60% of Medicare services covered under the contract.

(c) *Rural PSO.* To qualify as a rural PSO, a PSO must—

(1) Demonstrate to CMS that—

(i) It has available in the rural area, as defined in § 412.62(f) of this chapter, routine services including but not limited to primary care, routine specialty care, and emergency services; and

(ii) The level of use of providers outside the rural area is consistent with general referral patterns for the area; and

(2) Enroll Medicare beneficiaries, the majority of which reside in the rural area the PSO serves.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 35098, June 26, 1998; 65 FR 40327, June 29, 2000]

§ 422.354 Requirements for affiliated providers.

A PSO that consists of two or more providers must demonstrate to CMS'S satisfaction that it meets the following requirements:

(a) The providers are affiliated. For purposes of this subpart, providers are affiliated if, through contract, ownership, or otherwise—

(1) One provider, directly or indirectly, controls, is controlled by, or is under common control with another;

(2) Each provider is part of a lawful combination under which each shares substantial financial risk in connection with the PSO's operations;

(3) Both, or all, providers are part of a controlled group of corporations under section 1563 of the Internal Revenue Code of 1986; or

(4) Both, or all, providers are part of an affiliated service group under section 414 of that Code.

(b) Each affiliated provider of the PSO shares, directly or indirectly, substantial financial risk for the furnishing of services the PSO is obligated to provide under the contract.

(c) Affiliated providers, as a whole or in part, have at least a majority financial interest in the PSO.

(d) For purposes of paragraph(a)(1) of this section, control is presumed to exist if one party, directly or indirectly, owns, controls, or holds the power to vote, or proxies for, not less than 51 percent of the voting rights or governance right of another.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 35098, June 26, 1998]

§422.356 Determining substantial financial risk and majority financial interest.

(a) *Determining substantial financial risk.* The PSO must demonstrate to CMS's satisfaction that it apportions a significant part of the financial risk of the PSO enterprise under the M+C contract to each affiliated provider. The PSO must demonstrate that the financial arrangements among its affiliated providers constitute "substantial" risk in the PSO for each affiliated provider. The following mechanisms may constitute risk-sharing arrangements, and may have to be used in combination to demonstrate substantial financial risk in the PSO enterprise.

(1) Agreement by a provider to accept capitation payment for each Medicare enrollee.

(2) Agreement by a provider to accept as payment a predetermined percentage of the PSO premium or the PSO's revenue.

(3) The PSO's use of significant financial incentives for its affiliated providers, with the aim of achieving utilization management and cost containment goals. Permissible methods include the following:

(i) Affiliated providers agree to a withholding of a significant amount of the compensation due them, to be used for any of the following:

(A) To cover losses of the PSO.

(B) To cover losses of other affiliated providers.

(C) To be returned to the affiliated provider if the PSO meets its utilization management or cost containment goals for the specified time period.

(D) To be distributed among affiliated providers if the PSO meets its utilization management or cost-containment goals for the specified time period.

(ii) Affiliated providers agree to preestablished cost or utilization targets for the PSO and to subsequent significant financial rewards and penalties (which may include a reduction in payments to the provider) based on the PSO's performance in meeting the targets.

(4) Other mechanisms that demonstrate significant shared financial risk.

(b) *Determining majority financial interest.* Majority financial interest means maintaining effective control of the PSO.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 35098, June 26, 1998]

§422.370 Waiver of State licensure.

For an organization that seeks to contract to offer an M+C plan under this subpart, CMS may waive the State licensure requirement of section 1855(a)(1) of the Act if—

(a) The organization requests a waiver no later than November 1, 2002; and

(b) CMS determines there is a basis for a waiver under §422.372.

[63 FR 25376, May 7, 1998, as amended at 63 FR 35098, June 26, 1998]

§422.372 Basis for waiver of State licensure.

(a) *General rule.* Subject to this section and to paragraphs (a) and (e) of §422.374, CMS may waive the State licensure requirement if the organization has applied (except as provided in paragraph (b)(4) of this section) for the most closely appropriate State license or authority to conduct business as an M+C plan.

(b) *Basis for waiver of State licensure.* Any of the following may constitute a

basis for CMS's waiver of State licensure.

(1) *Failure to act timely on application.* The State failed to complete action on the licensing application within 90 days of the date the State received a substantially complete application.

(2) *Denial of application based on discriminatory treatment.* The State has—

(i) Denied the license application on the basis of material requirements, procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or

(ii) Required, as a condition of licensure that the organization offer any product or plan other than an M+C plan.

(3) *Denial of application based on different solvency requirements.* (i) The State has denied the application, in whole or in part, on the basis of the organization's failure to meet solvency requirements that are different from those set forth in §§ 422.380 through 422.390; or

(ii) CMS determines that the State has imposed, as a condition of licensure, any documentation or information requirements relating to solvency or other material requirements, procedures, or standards relating to solvency that are different from the requirements, procedures, or standards set forth by CMS to implement, monitor, and enforce §§ 422.380 through 422.390.

(4) *State declines to accept licensure application.* The appropriate State licensing authority has given the organization written notice that it will not accept its licensure application.

[63 FR 35098, June 26, 1998]

§ 422.374 Waiver request and approval process.

(a) *Substantially complete waiver request.* The organization must submit a substantially complete waiver request that clearly demonstrates and documents its eligibility for a waiver under § 422.372.

(b) CMS gives the organization written notice of granting or denial of waiver within 60 days of receipt of a substantially complete waiver request.

(c) *Subsequent waiver requests.* An organization that has had a waiver request denied, may submit subsequent waiver requests until November 1, 2002.

(d) *Effective date.* A waiver granted under § 422.370 will be effective on the effective date of the organization's M+C contract.

(e) *Consistency in application.* CMS reserves the right to revoke waiver eligibility if it subsequently determines that the organization's M+C application is significantly different from the application submitted by the organization to the State licensing authority.

[63 FR 25377, May 7, 1998, as amended at 63 FR 35098, June 26, 1998]

§ 422.376 Conditions of the waiver.

A waiver granted under this section is subject to the following conditions:

(a) *Limitation to State.* The waiver is effective only for the particular State for which it is granted and does not apply to any other State. For each State in which the organization wishes to operate without a State license, it must submit a waiver request and receive a waiver.

(b) *Limitation to 36-month period.* The waiver is effective for 36 months or through the end of the calendar year in which the 36 month period ends unless it is revoked based on paragraph (c) of this section.

(c) *Mid-period revocation.* During the waiver period (set forth in paragraph (b) of this section), the waiver is automatically revoked upon—

(1) Termination of the M+C contract;

(2) The organization's compliance with the State licensure requirement of section 1855(a)(1) of the Act; or

(3) The organization's failure to comply with § 422.378.

[63 FR 25377, May 7, 1998]

§ 422.378 Relationship to State law.

(a) *Preemption of State law.* Any provisions of State law that relate to the licensing of the organization and that prohibit the organization from providing coverage under a contract as specified in this subpart, are superseded.

(b) *Consumer protection and quality standards.* (1) A waiver of State licensure granted under this subpart is conditioned upon the organization's compliance with all State consumer protection and quality standards that—

(i) Would apply to the organization if it were licensed under State law;

(ii) Generally apply to other M+C organizations and plans in the State; and

(iii) Are consistent with the standards established under this part.

(2) The standards specified in paragraph (b)(1) of this section do not include any standard preempted under section 1856(b)(3)(B) of the Act.

(c) *Incorporation into contract.* In contracting with an organization that has a waiver of State licensure, CMS incorporates into the contract the requirements specified in paragraph (b) of this section.

(d) *Enforcement.* CMS may enter into an agreement with a State for the State to monitor and enforce compliance with the requirements specified in paragraph (b) of this section by an organization that has obtained a waiver under this subpart.

[63 FR 25377, May 7, 1998]

§422.380 Solvency standards.

General rule. A PSO or the legal entity of which the PSO is a component that has been granted a waiver under §422.370 must have a fiscally sound operation that meets the requirements of §§422.382 through 422.390.

[63 FR 25377, May 7, 1998]

§422.382 Minimum net worth amount.

(a) At the time an organization applies to contract with CMS as a PSO under this part, the organization must have a minimum net worth amount, as determined under paragraph (c) of this section, of:

(1) At least $1,500,000, except as provided in paragraph (a)(2) of this section.

(2) No less than $1,000,000 based on evidence from the organization's financial plan (under §422.384) demonstrating to CMS's satisfaction that the organization has available to it an administrative infrastructure that CMS considers appropriate to reduce, control or eliminate start-up administrative costs.

(b) After the effective date of a PSO's M+C contract, a PSO must maintain a minimum net worth amount equal to the greater of—

(1) One million dollars;

(2) Two percent of annual premium revenues as reported on the most recent annual financial statement filed with CMS for up to and including the first $150,000,000 of annual premiums and 1 percent of annual premium revenues on premiums in excess of $150,000,000;

(3) An amount equal to the sum of three months of uncovered health care expenditures as reported on the most recent financial statement filed with CMS; or

(4) Using the most recent financial statement filed with CMS, an amount equal to the sum of—

(i) Eight percent of annual health care expenditures paid on a non-capitated basis to non-affiliated providers; and

(ii) Four percent of annual health care expenditures paid on a capitated basis to non-affiliated providers plus annual health care expenditures paid on a non-capitated basis to affiliated providers.

(iii) Annual health care expenditures that are paid on a capitated basis to affiliated providers are not included in the calculation of the net worth requirement (regardless of downstream arrangements from the affiliated provider) under paragraphs (a) and (b)(4) of this section.

(c) *Calculation of the minimum net worth amount*—(1) *Cash requirement.* (i) At the time of application, the organization must maintain at least $750,000 of the minimum net worth amount in cash or cash equivalents.

(ii) After the effective date of a PSO's M+C contract, a PSO must maintain the greater of $750,000 or 40 percent of the minimum net worth amount in cash or cash equivalents.

(2) *Intangible assets.* An organization may include intangible assets, the value of which is based on Generally Accepted Accounting Principles (GAAP), in the minimum net worth amount calculation subject to the following limitations—

(i) *At the time of application.* (A) Up to 20 percent of the minimum net worth amount, provided at least $1,000,000 of the minimum net worth amount is met through cash or cash equivalents; or

(B) Up to 10 percent of the minimum net worth amount, if less than $1,000,000 of the minimum net worth amount is met through cash or cash equivalents, or if CMS has used its discretion under paragraph (a)(2) of this section.

(ii) *From the effective date of the contract.* (A) Up to 20 percent of the minimum net worth amount if the greater of $1,000,000 or 67 percent of the minimum net worth amount is met by cash or cash equivalents; or

(B) Up to ten percent of the minimum net worth amount if the greater of $1,000,000 or 67 percent of the minimum net worth amount is not met by cash or cash equivalents.

(3) *Health care delivery assets.* Subject to the other provisions of this section, a PSO may apply 100 percent of the GAAP depreciated value of health care delivery assets (HCDAs) to satisfy the minimum net worth amount.

(4) *Other assets.* A PSO may apply other assets not used in the delivery of health care provided that those assets are valued according to statutory accounting practices (SAP) as defined by the State.

(5) *Subordinated debts and subordinated liabilities.* Fully subordinated debt and subordinated liabilities are excluded from the minimum net worth amount calculation.

(6) *Deferred acquisition costs.* Deferred acquisition costs are excluded from the calculation of the minimum net worth amount.

[63 FR 25377, May 7, 1998, as amended at 64 FR 71678, Dec. 22, 1999]

§ 422.384 Financial plan requirement.

(a) *General rule.* At the time of application, an organization must submit a financial plan acceptable to CMS.

(b) *Content of plan.* A financial plan must include—

(1) A detailed marketing plan;

(2) Statements of revenue and expense on an accrual basis;

(3) Cash-flow statements;

(4) Balance sheets;

(5) Detailed justifications and assumptions in support of the financial plan including, where appropriate, certification of reserves and actuarial liabilities by a qualified actuary; and

(6) If applicable, statements of the availability of financial resources to meet projected losses.

(c) *Period covered by the plan.* A financial plan must—

(1) Cover the first 12 months after the estimated effective date of a PSO's M+C contract; or

(2) If the PSO is projecting losses, cover 12 months beyond the end of the period for which losses are projected.

(d) *Funding for projected losses.* Except for the use of guarantees, LOC, and other means as provided in §422.384(e), (f) and (g), an organization must have the resources for meeting projected losses on its balance sheet in cash or a form that is convertible to cash in a timely manner, in accordance with the PSO's financial plan.

(e) *Guarantees and projected losses.* Guarantees will be an acceptable resource to fund projected losses, provided that a PSO—

(1) Meets CMS's requirements for guarantors and guarantee documents as specified in §422.390; and

(2) Obtains from the guarantor cash or cash equivalents to fund the projected losses timely, as follows—

(i) Prior to the effective date of a PSO's M+C contract, the amount of the projected losses for the first two quarters;

(ii) During the first quarter and prior to the beginning of the second quarter of a PSO's M+C contract, the amount of projected losses through the end of the third quarter; and

(iii) During the second quarter and prior to the beginning of the third quarter of a PSO's M+C contract, the amount of projected losses through the end of the fourth quarter.

(3) If the guarantor complies with the requirements in paragraph (e)(2) of this section, the PSO, in the third quarter, may notify CMS of its intent to reduce the period of advance funding of projected losses. CMS will notify the PSO within 60 days of receiving the PSO's request if the requested reduction in the period of advance funding will not be accepted.

(4) If the guarantee requirements in paragraph (e)(2) of this section are not met, CMS may take appropriate action, such as requiring funding of projected losses through means other than a guarantee. CMS retains discretion to require other methods or timing of funding, considering factors such as the financial condition of the guarantor and the accuracy of the financial plan.

(f) *Letters of credit.* Letters of credit are an acceptable resource to fund projected losses, provided they are irrevocable, unconditional, and satisfactory to CMS. They must be capable of being promptly paid upon presentation of a sight draft under the letters of credt without further reference to any other agreement, document, or entity.

(g) *Other means.* If satisfactory to CMS, and for periods beginning one year after the effective date of a PSO's M+C contract, a PSO may use the following to fund projected losses—

(1) Lines of credit from regulated financial institutions;

(2) Legally binding agreements for capital contributions; or

(3) Legally binding agreements of a similar quality and reliability as permitted in paragraphs (g)(1) and (2) of this section.

(h) *Application of guarantees, Letters of credit or other means of funding projected losses.* Notwithstanding any other provision of this section, a PSO may use guarantees, letters of credit and, beginning one year after the effective date of a PSO's M+C contract, other means of funding projected losses, but only in a combination or sequence that CMS considers appropriate.

[63 FR 25378, May 7, 1998, as amended at 63 FR 35098, June 26, 1998; 64 FR 71678, Dec. 22, 1999]

§ 422.386 Liquidity.

(a) A PSO must have sufficient cash flow to meet its financial obligations as they become due and payable.

(b) To determine whether the PSO meets the requirement in paragraph (a) of this section, CMS will examine the following—

(1) The PSO's timeliness in meeting current obligations;

(2) The extent to which the PSO's current ratio of assets to liabilities is maintained at 1:1 including whether there is a declining trend in the current ratio over time; and

(3) The availability of outside financial resources to the PSO.

(c) If CMS determines that a PSO fails to meet the requirement in paragraph (b)(1) of this section, CMS will require the PSO to initiate corrective action and pay all overdue obligations.

(d) If CMS determines that a PSO fails to meet the requirement of paragraph (b)(2) of this section, CMS may require the PSO to initiate corrective action to—

(1) Change the distribution of its assets;

(2) Reduce its liabilities; or

(3) Make alternative arrangements to secure additional funding to restore the PSO's current ratio to 1:1.

(e) If CMS determines that there has been a change in the availability of outside financial resources as required by paragraph (b)(3) of this section, CMS requires the PSO to obtain funding from alternative financial resources.

[63 FR 25378, May 7, 1998, as amended at 64 FR 71678, Dec. 22, 1999]

§ 422.388 Deposits.

(a) *Insolvency deposit.* (1) At the time of application, an organization must deposit $100,000 in cash or securities (or any combination thereof) into an account in a manner that is acceptable to CMS.

(2) The deposit must be restricted to use in the event of insolvency to help assure continuation of services or pay costs associated with receivership or liquidation.

(3) At the time of the PSO's application for an M+C contract and, thereafter, upon CMS's request, a PSO must provide CMS with proof of the insolvency deposit, such proof to be in a form that CMS considers appropriate.

(b) *Uncovered expenditures deposit.* (1) If at any time uncovered expenditures exceed 10 percent of a PSO's total health care expenditures, then the PSO must place an uncovered expenditures deposit into an account with any organization or trustee that is acceptable to CMS.

(2) The deposit must at all times have a fair market value of an amount

that is 120 percent of the PSO's outstanding liability for uncovered expenditures for enrollees, including incurred, but not reported claims.

(3) The deposit must be calculated as of the first day of each month required and maintained for the remainder of each month required.

(4) If a PSO is not otherwise required to file a quarterly report, it must file a report within 45 days of the end of the calendar quarter with information sufficient to demonstrate compliance with this section.

(5) The deposit required under this section is restricted and in trust for CMS's use to protect the interests of the PSO's Medicare enrollees and to pay the costs associated with administering the insolvency. It may be used only as provided under this section.

(c) A PSO may use the deposits required under paragraphs (a) and (b) of this section to satisfy the PSO's minimum net worth amount required under § 422.382(a) and (b).

(d) All income from the deposits or trust accounts required under paragraphs (a) and (b) of this section, are considered assets of the PSO. Upon CMS's approval, the income from the deposits may be withdrawn.

(e) On prior written approval from CMS, a PSO that has made a deposit under paragraphs (a) or (b) of this section, may withdraw that deposit or any part thereof if—

(1) A substitute deposit of cash or securities of equal amount and value is made;

(2) The fair market value exceeds the amount of the required deposit; or

(3) The required deposit under paragraphs (a) or (b) of this section is reduced or eliminated.

[63 FR 25379, May 7, 1998]

§ 422.390 Guarantees.

(a) *General policy*. A PSO, or the legal entity of which the PSO is a component, may apply to CMS to use the financial resources of a guarantor for the purpose of meeting the requirements in § 422.384. CMS has the discretion to approve or deny approval of the use of a guarantor.

(b) *Request to use a guarantor.* To apply to use the financial resources of a guarantor, a PSO must submit to CMS—

(1) Documentation that the guarantor meets the requirements for a guarantor under paragraph (c) of this section; and

(2) The guarantor's independently audited financial statements for the current year-to-date and for the two most recent fiscal years. The financial statements must include the guarantor's balance sheets, profit and loss statements, and cash flow statements.

(c) *Requirements for guarantor.* To serve as a guarantor, an organization must meet the following requirements:

(1) Be a legal entity authorized to conduct business within a State of the United States.

(2) Not be under Federal or State bankruptcy or rehabilitation proceedings.

(3) Have a net worth (not including other guarantees, intangibles and restricted reserves) equal to three times the amount of the PSO guarantee.

(4) If the guarantor is regulated by a State insurance commissioner, or other State official with authority for risk-bearing entities, it must meet the net worth requirement in § 422.390(c)(3) with all guarantees and all investments in and loans to organizations covered by guarantees excluded from its assets.

(5) If the guarantor is not regulated by a State insurance commissioner, or other similar State official it must meet the net worth requirement in § 422.390(c)(3) with all guarantees and all investments in and loans to organizations covered by a guarantee and to related parties (subsidiaries and affiliates) excluded from its assets.

(d) *Guarantee document.* If the guarantee request is approved, a PSO must submit to CMS a written guarantee document signed by an appropriate authority of the guarantor. The guarantee document must—

(1) State the financial obligation covered by the guarantee;

(2) Agree to—

(i) Unconditionally fulfill the financial obligation covered by the guarantee; and

(ii) Not subordinate the guarantee to any other claim on the resources of the guarantor;

(3) Declare that the guarantor must act on a timely basis, in any case not more than 5 business days, to satisfy the financial obligation covered by the guarantee; and

(4) Meet other conditions as CMS may establish from time to time.

(e) *Reporting requirement.* A PSO must submit to CMS the current internal financial statements and annual audited financial statements of the guarantor according to the schedule, manner, and form that CMS requests.

(f) *Modification, substitution, and termination of a guarantee.* A PSO cannot modify, substitute or terminate a guarantee unless the PSO—

(1) Requests CMS's approval at least 90 days before the proposed effective date of the modification, substitution, or termination;

(2) Demonstrates to CMS's satisfaction that the modification, substitution, or termination will not result in insolvency of the PSO; and

(3) Demonstrates how the PSO will meet the requirements of this section.

(g) *Nullification.* If at any time the guarantor or the guarantee ceases to meet the requirements of this section, CMS will notify the PSO that it ceases to recognize the guarantee document. In the event of this nullification, a PSO must—

(1) Meet the applicable requirements of this section within 15 business days; and

(2) If required by CMS, meet a portion of the applicable requirements in less than the time period granted in paragraph (g)(1) of this section.

[63 FR 25379, May 7, 1998]

Subpart I—Organization Compliance With State Law and Preemption by Federal Law

SOURCE: 63 FR 35099, June 26, 1998, unless otherwise noted.

§422.400 State licensure requirement.

Except in the case of a PSO granted a waiver under subpart H of this part, each M+C organization must—

(a) Be licensed under State law, or otherwise authorized to operate under State law, as a risk-bearing entity (as defined in §422.2) eligible to offer health insurance or health benefits coverage in each State in which it offers one or more M+C plans;

(b) If not commercially licensed, obtain certification from the State that the organization meets a level of financial solvency and such other standards as the State may require for it to operate as an M+C organization; and

(c) Demonstrate to CMS that—

(1) The scope of its license or authority allows the organization to offer the type of M+C plan or plans that it intends to offer in the State; and

(2) If applicable, it has obtained the State certification required under paragraph (b) of this section.

§422.402 Federal preemption of State law.

(a) *General preemption.* Except as provided in paragraph (b) of this section, the rules, contract requirements, and standards established under this part supersede any State laws, regulations, contract requirements, or other standards that would otherwise apply to M+C organizations and their M+C plans only to the extent that such State laws are inconsistent with the standards established under this part. This preemption of State laws and other standards applies only to coverage pursuant to an M+C contract, and does not extend to benefits outside of such contract or to individuals who are not M+C enrollees of an organization with an M+C contract.

(b) *Specific preemption.* As they might otherwise apply to the M+C plans of an M+C organization in a State, State laws and regulations pertaining to the following areas are specifically preempted by this part:

(1) Benefit requirements, such as mandating the inclusion in an M+C plan of a particular service, or specifying the scope or duration of a service (for example, length of hospital stay, number of home health visits). State cost-sharing standards with respect to any benefits are preempted only if they are inconsistent with this part, as provided for in paragraph (a) of this section.

(2) Requirements relating to inclusion or treatment of providers and suppliers.

(3) Coverage determinations (including related appeal and grievance processes for all benefits included under an M+C contract). Determinations on issues other than whether a service is covered under an M+C contract, and the extent of enrollee liability under the M+C plan for such a service, are not considered coverage determinations for purposes of this paragraph.

(c) Except as provided in paragraphs (a) and (b) of this section, nothing in this section may be construed to affect or modify the provisions of any other law or regulation that imposes or preempts a specific State authority.

§ 422.404 State premium taxes prohibited.

(a) *Basic rule.* No premium tax, fee, or other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, or any of their political subdivision or other governmental authorities with respect to any payment CMS makes on behalf of M+C enrollees under subpart F of this part.

(b) *Construction.* Nothing in this section shall be construed to exempt any M+C organization from taxes, fees, or other monetary assessments related to the net income or profit that accrues to, or is realized by, the organization from business conducted under this part, if that tax, fee, or payment is applicable to a broad range of business activity.

Subpart J [Reserved]

Subpart K—Contracts With Medicare+Choice Organizations

SOURCE: 63 FR 35099, June 26, 1998, unless otherwise noted.

§ 422.500 Definitions.

For purposes of this subpart, the following definitions apply:

Business transaction means any of the following kinds of transactions:

(1) Sale, exchange, or lease of property.

(2) Loan of money or extension of credit.

(3) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(i) Salaries paid to employees for services performed in the normal course of their employment; or

(ii) Health services furnished to the M+C organization's enrollees by hospitals and other providers, and by M+C organization staff, medical groups, or independent practice associations, or by any combination of those entities.

Clean claim means—

(1) A claim that has no defect, impropriety, lack of any required substantiating documentation (consistent with §422.257(d)) or particular circumstance requiring special treatment that prevents timely payment; and

(2) A claim that otherwise conforms to the clean claim requirements for equivalent claims under original Medicare.

Downstream entity means any party that enters into an acceptable written arrangement below the level of the arrangement between an M+C organization (or contract applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

First tier entity means any party that enters into an acceptable written arrangement with an M+C organization or contract applicant to provide administrative services or health care services for a Medicare eligible individual.

Party in interest includes the following:

(1) Any director, officer, partner, or employee responsible for management or administration of an M+C organization.

(2) Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

(3) In the case of an M+C organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law.

(4) Any entity in which a person described in paragraph (1), (2), or (3) of this definition:

(i) Is an officer, director, or partner; or

(ii) Has the kind of interest described in paragraphs (1), (2), or (3) of this definition.

(5) Any person that directly or indirectly controls, is controlled by, or is under common control with, the M+C organization.

(6) Any spouse, child, or parent of an individual described in paragraph (1), (2), or (3) of this definition.

Related entity means any entity that is related to the M+C organization by common ownership or control and—

(1) Performs some of the M+C organization's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the M+C organization at a cost of more than $2,500 during a contract period.

Significant business transaction means any business transaction or series of transactions of the kind specified in the above definition of "business transaction" that, during any fiscal year of the M+C organization, have a total value that exceeds $25,000 or 5 percent of the M+C organization's total operating expenses, whichever is less.

[65 FR 35099, June 26, 1998, as amended at 65 FR 40327, June 29, 2000]

§422.501 General provisions.

(a) *Basic rule.* In order to qualify as an M+C organization, enroll beneficiaries in any M+C plans it offers, and be paid on behalf of Medicare beneficiaries enrolled in those plans, an M+C organization must enter into a contract with CMS.

(b) *Conditions necessary to contract as an M+C organization.* Any entity seeking to contract as an M+C organization must:

(1) Be licensed by the State as a risk bearing entity in each State in which it seeks to offer an M+C plan as defined in §422.2.

(2) Meet the minimum enrollment requirements of §422.514, unless waived under §422.514(b).

(3) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following:

(i) A policy making body that exercises oversight and control over the M+C organization's policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees.

(ii) Personnel and systems sufficient for the M+C organization to organize, plan, control, and evaluate financial and marketing activities, the furnishing of services, the quality assurance program, and the administrative and management aspects of the organization.

(iii) At a minimum, an executive manager whose appointment and removal are under the control of the policy making body.

(iv) A fidelity bond or bonds, procured and maintained by the M+C organization, in an amount fixed by its policymaking body but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the M+C organization.

(v) Insurance policies or other arrangements, secured and maintained by the M+C organization and approved by CMS to insure the M+C organization against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.

(vi) A compliance plan that consists of the following:

(A) Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards.

(B) The designation of a compliance officer and compliance committee that are accountable to senior management.

(C) Effective training and education between the compliance officer and organization employees.

(D) Effective lines of communication between the compliance officer and the organization's employees.

(E) Enforcement of standards through well-publicized disciplinary guidelines.

(F) Provision for internal monitoring and auditing.

(G) Procedures for ensuring prompt response to detected offenses and development of corrective action initiatives relating to the organization's M+C contract.

(4) Not accept new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an M+C plan.

(5) The M+C organization's contract must not have been terminated by CMS under §422.510 within the past 2 years unless—

(i) During the 6-month period beginning on the date the organization notified CMS of the intention to terminate the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing M+C payments in the payment area or areas at issue; or

(ii) CMS has otherwise determined that circumstances warrant special consideration.

(c) *Contracting authority.* Under the authority of section 1857(c)(5) of the Act, CMS may enter into contracts under this part without regard to Federal and Departmental acquisition regulations set forth in title 48 of the CFR and provisions of law or other regulations relating to the making, performance, amendment, or modification of contracts of the United States if CMS determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program.

(d) *Protection against fraud and beneficiary protections.* (1) CMS annually audits the financial records (including data relating to Medicare utilization, costs, and computation of the ACR) of at least one-third of the M+C organizations offering M+C plans. These auditing activities are subject to monitoring by the Comptroller General.

(2) Each contract under this section must provide that CMS, or any person or organization designated by CMS has the right to:

(i) Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the M+C contract;

(ii) Inspect or otherwise evaluate the facilities of the organization when there is reasonable evidence of some need for such inspection; and

(iii) Audit and inspect any books, contracts, and records of the M+C organization that pertain to—

(A) The ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or

(B) Services performed or determinations of amounts payable under the contract.

(e) *Severability of contracts.* The contract must provide that, upon CMS's request—

(1) The contract will be amended to exclude any M+C plan or State-licensed entity specified by CMS; and

(2) A separate contract for any such excluded plan or entity will be deemed to be in place when such a request is made.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40327, June 29, 2000]

§ 422.502 Contract provisions.

The contract between the M+C organization and CMS must contain the following provisions:

(a) *Agreement to comply with regulations and instructions.* The M+C organization agrees to comply with all the applicable requirements and conditions set forth in this part and in general instructions. An M+C organization's compliance with paragraphs (a)(1) through (a)(13) of this section is material to performance of the contract. The M+C organization agrees—

(1) To accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as provided in subpart B of this part.

(2) That it will comply with the prohibition in §422.110 on discrimination in beneficiary enrollment.

(3) To provide—

(i) The basic benefits as required under §422.101 and, to the extent applicable, supplemental benefits under §422.102; and

(ii) Access to benefits as required under subpart C of this part;

(iii) In a manner consistent with professionally recognized standards of health care, all benefits covered by Medicare.

(4) To disclose information to beneficiaries in the manner and the form prescribed by CMS as required under § 422.111;

(5) To operate a quality assurance and performance improvement program and have an agreement for external quality review as required under subpart D of this part;

(6) To comply with all applicable provider requirements in subpart E of this part, including provider certification requirements, anti-discrimination requirements, provider participation and consultation requirements, the prohibition on interference with provider advice, limits on provider indemnification, rules governing payments to providers, and limits on physician incentive plans;

(7) To comply with all requirements in subpart M of this part governing coverage determinations, grievances, and appeals;

(8) To comply with the reporting requirements in § 422.516 and the requirements in § 422.257 for submitting encounter data to CMS;

(9) That it will be paid under the contract in accordance with the payment rules in subpart F of this part;

(10) To develop its annual ACR, and submit all required information on premiums, benefits, and cost-sharing by May 1, as provided in subpart G of this part;

(11) That its contract may not be renewed or may be terminated in accordance with this subpart and subpart N of this part.

(12) To comply with all requirements that are specific to a particular type of M+C plan, such as the special rules for private fee-for-service plans in §§ 422.114 and 422.216 and the MSA requirements in §§ 422.56, 422.103, and 422.262; and

(13) To comply with the confidentiality and enrollee record accuracy requirements in § 422.118.

(14) An M+C organization's compliance with paragraphs (a)(1) through (a)(13) and (c) of this section is material to performance of the contract.

(b) *Communication with CMS.* The M+C organization must have the capacity to communicate with CMS electronically.

(c) *Prompt payment.* The M+C organization must comply with the prompt payment provisions of § 422.520 and with instructions issued by CMS, as they apply to each type of plan included in the contract.

(d) *Maintenance of records.* The M+C organization agrees to maintain for 6 years books, records, documents, and other evidence of accounting procedures and practices that—

(1) Are sufficient to do the following:

(i) Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the ACR) of M+C organizations.

(ii) Enable CMS to inspect or otherwise evaluate the quality, appropriateness and timeliness of services performed under the contract, and the facilities of the organization.

(iii) Enable CMS to audit and inspect any books and records of the M+C organization that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or determinations of amounts payable under the contract.

(iv) Properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the ACR proposal.

(v) Establish component rates of the ACR for determining additional and supplementary benefits.

(vi) Determine the rates utilized in setting premiums for State insurance agency purposes and for other government and private purchasers; and

(2) Include at least records of the following:

(i) Ownership and operation of the M+C organization's financial, medical, and other record keeping systems.

(ii) Financial statements for the current contract period and six prior periods.

(iii) Federal income tax or informational returns for the current contract period and six prior periods.

(iv) Asset acquisition, lease, sale, or other action.

(v) Agreements, contracts, and subcontracts.

(vi) Franchise, marketing, and management agreements.

(vii) Schedules of charges for the M+C organization's fee-for-service patients.

(viii) Matters pertaining to costs of operations.

(ix) Amounts of income received by source and payment.

(x) Cash flow statements.

(xi) Any financial reports filed with other Federal programs or State authorities.

(e) *Access to facilities and records.* The M+C organization agrees to the following:

(1) HHS, the Comptroller General, or their designee may evaluate, through inspection or other means—

(i) The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;

(ii) The facilities of the M+C organization; and

(iii) The enrollment and disenrollment records for the current contract period and six prior periods.

(2) HHS, the Comptroller General, or their designees may audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of the M+C organization, related entity, contractor, subcontractor, or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.

(3) The M+C organization agrees to make available, for the purposes specified in paragraph (d) of this section, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require.

(4) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 6 years from the final date of the contract period or completion of audit, whichever is later unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the M+C organization at least 30 days before the normal disposition date;

(ii) There has been a termination, dispute, or fraud or similar fault by the M+C organization, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault; or

(iii) CMS determines that there is a reasonable possibility of fraud, in which case it may inspect, evaluate, and audit the M+C organization at any time.

(f) *Disclosure of information.* The M+C organization agrees to submit—

(1) To CMS, certified financial information that must include the following:

(i) Such information as CMS may require demonstrating that the organization has a fiscally sound operation.

(ii) Such information as CMS may require pertaining to the disclosure of ownership and control of the M+C organization.

(2) To CMS, all information that is necessary for CMS to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining Medicare services. This information includes, but is not limited to:

(i) The benefits covered under an M+C plan;

(ii) The M+C monthly basic beneficiary premium and M+C monthly supplemental beneficiary premium, if any, for the plan or in the case of an MSA plan, the M+C monthly MSA premium.

(iii) The service area and continuation area, if any, of each plan and the enrollment capacity of each plan;

(iv) Plan quality and performance indicators for the benefits under the plan including —

(A) Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;

(B) Information on Medicare enrollee satisfaction;

(C) Information on health outcomes;

(D) The recent record regarding compliance of the plan with requirements of this part, as determined by CMS; and

(E) Other information determined by CMS to be necessary to assist beneficiaries in making an informed choice among M+C plans and traditional Medicare;

(v) Information about beneficiary appeals and their disposition;

(vi) Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization;

(vii) For M+C organizations offering an MSA plan, information specified by CMS for CMS's use in preparing its report to the Congress on the MSA demonstration, including data specified by CMS in the areas of selection, use of preventative care, and access to services.

(viii) To CMS, any other information deemed necessary by CMS for the administration or evaluation of the Medicare program.

(3) To its enrollees all informational requirements under §422.64 and, upon an enrollee's, request the financial disclosure information required under §422.516.

(g) *Beneficiary financial protections.* The M+C organization agrees to comply with the following requirements:

(1) Each M+C organization must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability (for example, as a result of an organization's insolvency or other financial difficulties) for payment of any fees that are the legal obligation of the M+C organization. To meet this requirement, the M+C organization must—

(i) Ensure that all contractual or other written arrangements with providers prohibit the organization's providers from holding any beneficiary enrollee liable for payment of any such fees; and

(ii) Indemnify the beneficiary enrollee for payment of any fees that are the legal obligation of the M+C organization for services furnished by providers that do not contract, or that have not otherwise entered into an agreement with the M+C organization, to provide services to the organization's beneficiary enrollees.

(2) The M+C organization must provide for continuation of enrollee health care benefits—

(i) For all enrollees, for the duration of the contract period for which CMS payments have been made; and

(ii) For enrollees who are hospitalized on the date its contract with CMS terminates, or, in the event of an insolvency, through discharge.

(3) In meeting the requirements of this paragraph, other than the provider contract requirements specified in paragraph (g)(1)(i) of this section, the M+C organization may use—

(i) Contractual arrangements;

(ii) Insurance acceptable to CMS;

(iii) Financial reserves acceptable to CMS; or

(iv) Any other arrangement acceptable to CMS.

(h) *Requirements of other laws and regulations.* (1) The M+C organization agrees to comply with—

(i) Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 84;

(ii) The Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91;

(iii) The Rehabilitation Act of 1973;

(iv) The Americans With Disabilities Act;

(v) Other laws applicable to recipients of Federal funds; and

(vi) All other applicable laws and rules.

(2) M+C organizations receiving Federal payments under M+C contracts, and related entities, contractors, and subcontractors paid by an M+C organization to fulfill its obligations under its M+C contract are subject to certain laws that are applicable to individuals and entities receiving Federal funds. M+C organizations must inform all related entities, contractors and subcontractors that payments that they receive are, in whole or in part, from Federal funds.

(i) *M+C organization relationship with related entities, contractors, and subcontractors.* (1) Notwithstanding any relationship(s) that the M+C organization may have with related entities, contractors, or subcontractors, the M+C organization maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.

(2) The M+C organization agrees to require all related entities, contractors, or subcontractors to agree that—

(i) HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent contracts, books, documents, papers, and records of the related entity(s), contractor(s), or subcontractor(s) involving transactions related to the M+C contract; and

(ii) HHS', the Comptroller General's, or their designee's right to inspect, evaluate, and audit any pertinent information for any particular contract period will exist through 6 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(3) All contracts or written arrangements between M+C organizations and providers, related entities, contractors, subcontractors, first tier and downstream entities must contain the following:

(i) Enrollee protection provisions that provide, consistent with paragraph (g)(1) of this section, arrangements that prohibit providers from holding an enrollee liable for payment of any fees that are the obligation of the M+C organization.

(ii) Accountability provisions that indicate that—

(A) The M+C organization oversees and is accountable to CMS for any functions or responsibilities that are described in these standards; and

(B) The M+C organization may only delegate activities or functions to a provider, related entity, contractor, or subcontractor in a manner consistent with requirements set forth at paragraph (i)(4) of this section.

(iii) A provision requiring that any services or other activity performed by a related entity, contractor, subcontractor, or first-tier or downstream entity in accordance with a contract or written agreement are consistent and comply with the M+C organization's contractual obligations.

(4) If any of the M+C organizations' activities or responsibilities under its contract with CMS are delegated to other parties, the following requirements apply to any related entity, contractor, subcontractor, or provider:

(i) Written arrangements must specify delegated activities and reporting responsibilities.

(ii) Written arrangements must either provide for revocation of the delegation activities and reporting requirements or specify other remedies in instances where CMS or the M+C organization determine that such parties have not performed satisfactorily.

(iii) Written arrangements must specify that the performance of the parties is monitored by the M+C organization on an ongoing basis.

(iv) Written arrangements must specify that either—

(A) The credentials of medical professionals affiliated with the party or parties will be either reviewed by the M+C organization; or

(B) The credentialing process will be reviewed and approved by the M+C organization and the M+C organization must audit the credentialing process on an ongoing basis.

(v) All contracts or written arrangements must specify that the related entity, contractor, or subcontractor must comply with all applicable Medicare laws, regulations, and CMS instructions.

(5) If the M+C organization delegates selection of the providers, contractors, or subcontractor to another organization, the M+C organization's written arrangements with that organization must state that the CMS-contracting M+C organization retains the right to approve, suspend, or terminate any such arrangement.

(j) *Additional contract terms.* The M+C organization agrees to include in the contract such other terms and conditions as CMS may find necessary and appropriate in order to implement requirements in this part.

(k) *Severability of contracts.* The contract must provide that, upon CMS's request—

(1) The contract will be amended to exclude any M+C plan or State-licensed entity specified by CMS; and

(2) A separate contract for any such excluded plan or entity will be deemed to be in place when such a request is made.

(l) *Certification of data that determine payment.* As a condition for receiving a monthly payment under subpart F of this part, the M+C organization agrees that its chief executive officer (CEO),

chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of relevant data that CMS requests. Such data include specified enrollment information, encounter data, and other information that CMS may specify.

(1) The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify that each enrollee for whom the organization is requesting payment is validly enrolled in an M+C plan offered by the organization and the information relied upon by CMS in determining payment (based on best knowledge, information, and belief) is accurate, complete, and truthful.

(2) The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information, and belief) that the encounter data it submits under §422.257 are accurate, complete, and truthful.

(3) If such encounter data are generated by a related entity, contractor, or subcontractor of an M+C organization, such entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data.

(4) The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information, and belief) that the information in its ACR submission is accurate, complete, and truthful and fully conforms to the requirements in §422.310.

[63 FR 35099, June 26, 1998; 63 FR 52614, Oct. 1, 1998, as amended at 64 FR 7980, Feb. 17, 1999; 65 FR 40327, June 29, 2000]

§422.504 Effective date and term of contract.

(a) *Effective date.* The contract is effective on the date specified in the contract between the M+C organization and CMS and, for a contract that provides for coverage under an MSA plan, not earlier than January 1999.

(b) *Term of contract.* Each contract is for a period of at least 12 months.

(c) *Renewal of contract.* In accordance with §422.506, contracts are renewed annually only if—

(1) CMS informs the M+C organization that it authorizes a renewal; and

(2) The M+C organization has not provided CMS with a notice of intention not to renew.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000]

§422.506 Nonrenewal of contract.

(a) *Nonrenewal by an M+C organization.* (1) An M+C organization may elect not to renew its contract with CMS as of the end of the term of the contract for any reason provided it meets the timeframes for doing so set forth in paragraphs (a)(2) and (a)(3) of this section.

(2) If an M+C organization does not intend to renew its contract, it must notify—

(i) CMS in writing, by July 1 of the year in which the contract would end;

(ii) Each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. This notice must include a written description of alternatives available for obtaining Medicare services within the service area, including alternative M+C plans, Medigap options, and original Medicare and must receive CMS approval.

(iii) The general public, at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community located in the M+C organization's service area.

(3) CMS may accept a nonrenewal notice submitted after July 1 if—

(i) The M+C organization notifies its Medicare enrollees and the public in accordance with paragraph (a)(2)(ii) and (a)(2)(iii) of this section; and

(ii) Acceptance is not inconsistent with the effective and efficient administration of the Medicare program.

(4) If an M+C organization does not renew a contract under this paragraph (a), CMS will not enter into a contract with the organization for 2 years unless there are special circumstances that

warrant special consideration, as determined by CMS.

(b) *CMS decision not to renew.* (1) CMS may elect not to authorize renewal of a contract for any of the following reasons:

(i) The M+C organization has not fully implemented or shown discernable progress in implementing quality improvement projects as defined in §422.152(d).

(ii) For any of the reasons listed in §422.510(a), which would also permit CMS to terminate the contract.

(iii) The M+C organization has committed any of the acts in §422.752(a) that would support the imposition of intermediate sanctions or civil money penalties under subpart O of this part.

(2) *Notice.* CMS provides notice of its decision whether to authorize renewal of the contract as follows:

(i) To the M+C organization by May 1 of the contract year.

(ii) If CMS decides not to authorize a renewal of the contract, to the M+C organization's Medicare enrollees by mail at least 90 days before the end of the current calendar year.

(iii) If CMS decides not to authorize a renewal of the contract, to the general public at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the M+C organization's service area.

(3) *Notice of appeal rights.* CMS gives the M+C organization written notice of its right to appeal the decision not to renew in accordance with §422.644.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 67 FR 13289, Mar. 22, 2002]

§422.508 Modification or termination of contract by mutual consent.

(a) A contract may be modified or terminated at any time by written mutual consent.

(1) If the contract is terminated by mutual consent, except as provided in paragraph (b) of this section, the M+C organization must provide notice to its Medicare enrollees and the general public as provided in §422.512(b)(2) and (b)(3).

(2) If the contract is modified by mutual consent, the M+C organization must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification within timeframes specified by CMS.

(b) If the contract terminated by mutual consent is replaced the day following such termination by a new M+C contract, the M+C organization is not required to provide the notice specified in paragraph (a)(1) of this section.

§422.510 Termination of contract by CMS.

(a) *Termination by CMS.* CMS may terminate a contract for any of the following reasons:

(1) The M+C organization has failed substantially to carry out the terms of its contract with CMS.

(2) The M+C organization is carrying out its contract with CMS in a manner that is inconsistent with the effective and efficient implementation of this part.

(3) CMS determines that the M+C organization no longer meets the requirements of this part for being a contracting organization.

(4) The M+C organization commits or participates in fraudulent or abusive activities affecting the Medicare program, including submission of fraudulent data.

(5) The M+C organization experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists.

(6) The M+C organization substantially fails to comply with the requirements in subpart M of this part relating to grievances and appeals.

(7) The M+C organization fails to provide CMS with valid encounter data as required under §422.257.

(8) The M+C organization fails to implement an acceptable quality assessment and performance improvement program as required under subpart D of this part.

(9) The M+C organization substantially fails to comply with the prompt payment requirements in §422.520.

(10) The M+C organization substantially fails to comply with the service

access requirements in §422.112 or §422.114.

(11) The M+C organization fails to comply with the requirements of §422.208 regarding physician incentive plans.

(12) The M+C organization substantially fails to comply with the marketing requirements in §422.80.

(b) *Notice.* If CMS decides to terminate a contract for reasons other than the grounds specified in §422.510(a)(5), it gives notice of the termination as follows:

(1) *Termination of contract by CMS.* (i) CMS notifies the M+C organization in writing 90 days before the intended date of the termination.

(ii) The M+C organization notifies its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.

(iii) The M+C organization notifies the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the M+C organization's service area.

(2) *Immediate termination of contract by CMS.* (i) For terminations based on violations prescribed in §422.510(a)(5), CMS notifies the M+C organization in writing that its contract has been terminated effective the date of the termination decision by CMS. If termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the M+C organization covering the period of the month following the contract termination.

(ii) CMS notifies the M+C organization's Medicare enrollees in writing of CMS's decision to terminate the M+C organization's contract. This notice occurs no later than 30 days after CMS notifies the plan of its decision to terminate the M+C contract. CMS simultaneously informs the Medicare enrollees of alternative options for obtaining Medicare services, including alternative M+C organizations in a similar geographic area and original Medicare.

(iii) CMS notifies the general public of the termination no later than 30 days after notifying the plan of CMS's decision to terminate the M+C contract. This notice is published in one or more newspapers of general circulation in each community or county located in the M+C organization's service area.

(c) *Corrective action plan*—(1) *General.* Before terminating a contract for reasons other than the grounds specified in paragraph (a)(5) of this section, CMS provides the M+C organization with reasonable opportunity to develop and receive CMS approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination.

(2) *Exception.* If a contract is terminated under §422.510(a)(5), the M+C organization will not have the opportunity to submit a corrective action plan.

(d) *Appeal rights.* If CMS decides to terminate a contract, it sends written notice to the M+C organization informing it of its termination appeal rights in accordance with subpart N of this part.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000]

§422.512 Termination of contract by the M+C organization.

(a) *Cause for termination.* The M+C organization may terminate the M+C contract if CMS fails to substantially carry out the terms of the contract.

(b) *Notice.* The M+C organization must give advance notice as follows:

(1) To CMS, at least 90 days before the intended date of termination. This notice must specify the reasons why the M+C organization is requesting contract termination.

(2) To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining Medicare services within the services area, including alternative M+C plans, Medigap options, original Medicare and must receive CMS approval.

(3) To the general public at least 60 days before the termination effective date by publishing an CMS-approved notice in one or more newspapers of general circulation in each community or county located in the M+C organization's geographic area.

(c) *Effective date of termination.* The effective date of the termination is determined by CMS and is at least 90 days after the date CMS receives the M+C organization's notice of intent to terminate.

(d) *CMS's liability.* CMS's liability for payment to the M+C organization ends as of the first day of the month after the last month for which the contract is in effect.

(e) *Effect of termination by the organization.* CMS does not enter into an agreement with an organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

[63 FR 35099, June 26, 1998, as amended at 67 FR 13288, Mar. 22, 2002]

§ 422.514 Minimum enrollment requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, CMS does not enter into a contract under this subpart unless the organization meets the following minimum enrollment requirement—

(1) At least 5,000 individuals (or 1,500 individuals if the organization is a PSO) are enrolled for the purpose of receiving health benefits from the organization; or

(2) At least 1,500 individuals (or 500 individuals if the organization is a PSO) are enrolled for purposes of receiving health benefits from the organization and the organization primarily serves individuals residing outside of urbanized areas as defined in § 412.62(f) (or, in the case of a PSO, the PSO meets the requirements in § 422.352(c)).

(3) Except as provided for in paragraph (b) of this section, an M+C organization must maintain a minimum enrollment as defined in paragraphs (a)(1) and (a)(2) of this section for the duration of its contract.

(b) *Minimum enrollment waiver.* (1) For a contract applicant or M+C organization that does not meet the applicable requirement of paragraph (a) of this section at application for an M+C contract or during the first 3 years of the contract, CMS may waive the minimum enrollment requirement as provided for below. To receive a waiver, a contract applicant or M+C organization must demonstrate to CMS's satisfaction that it is capable of administering and managing an M+C contract and is able to manage the level of risk required under the contract. Factors that CMS takes into consideration in making this evaluation include the extent to which—

(i) The contract applicant or M+C organization's management and providers have previous experience in managing and providing health care services under a risk-based payment arrangement to at least as many individuals as the applicable minimum enrollment for the entity as described in paragraph (a) of this section, or

(ii) The contract applicant or M+C organization has the financial ability to bear financial risk under an M+C contract. In determining whether an organization is capable of bearing risk, CMS considers factors such as the organization's management experience as described in paragraph (b)(1)(i) of this section and stop-loss insurance that is adequate and acceptable to CMS; and

(iii) The contract applicant or M+C organization is able to establish a marketing and enrollment process that allows it to meet the applicable enrollment requirement specified in paragraph (a) of this section before completion of the third contract year.

(2) If an M+C organization fails to meet the enrollment requirement in the first year, CMS may waive the minimum requirements for another year provided that the organization—

(i) Requests an additional minimum enrollment waiver no later than 120 days before the end of the first year;

(ii) Continues to demonstrate it is capable of administering and managing an M+C contract and is able to manage the level of risk; and,

(iii) Demonstrates an acceptable marketing and enrollment process. Enrollment projections for the second year of the waiver will become the organization's transitional enrollment standard.

(3) If an M+C organization fails to meet the enrollment requirement in the second year, CMS may waive the minimum requirements for the third year only if the organization has attained the transitional enrollment

standard as described in paragraph (b)(2)(iii) of this section.

(c) Failure to meet enrollment requirements. CMS may elect not to renew its contract with an M+C organization that fails to meet the applicable enrollment requirement in paragraph (a) of this section

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000]

§422.516 Reporting requirements.

(a) *Required information.* Each M+C organization must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information with respect to the following:

(1) The cost of its operations.

(2) The patterns of utilization of its services.

(3) The availability, accessibility, and acceptability of its services.

(4) To the extent practical, developments in the health status of its enrollees.

(5) Information demonstrating that the M+C organization has a fiscally sound operation.

(6) Other matters that CMS may require.

(b) *Significant business transactions.* Each M+C organization must report to CMS annually, within 120 days of the end of its fiscal year (unless for good cause shown, CMS authorizes an extension of time), the following:

(1) A description of significant business transactions (as defined in §422.500) between the M+C organization and a party in interest.

(2) With respect to those transactions—

(i) A showing that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or

(ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.

(3) A combined financial statement for the M+C organization and a party in interest if either of the following conditions is met:

(i) Thirty-five percent or more of the costs of operation of the M+C organization go to a party in interest.

(ii) Thirty-five percent or more of the revenue of a party in interest is from the M+C organization.

(c) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(3) of this section must display in separate columns the financial information for the M+C organization and each of the parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) The statements must have been examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(4) Upon written request from an M+C organization showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in this paragraph (c) with respect to a particular entity.

(d) *Reporting and disclosure under ERISA.* (1) For any employees' health benefits plan that includes an M+C organization in its offerings, the M+C organization must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the particular M+C organization) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) The M+C organization must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term "administrator" is defined in ERISA.

(e) *Loan information.* Each organization must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

(f) *Enrollee access to Information.* Each M+C organization must make the information reported to CMS under §422.502(f)(1) available to its enrollees upon reasonable request.

§ 422.520 Prompt payment by M+C organization.

(a) *Contract between CMS and the M+C organization.*

(1) The contract between CMS and the M+C organization must provide that the M+C organization will pay 95 percent of the "clean claims" within 30 days of receipt if they are submitted by, or on behalf of, an enrollee of an M+C private fee-for-service plan or are claims for services that are not furnished under a written agreement between the organization and the provider.

(2) The M+C organization must pay interest on clean claims that are not paid within 30 days in accordance with sections 1816(c)(2)(B) and 1842(c)(2)(B).

(3) All other claims must be paid or denied within 60 calendar days from the date of the request.

(b) *Contracts between M+C organizations and providers and suppliers.* Contracts or other written agreements between M+C organizations and providers must contain a prompt payment provision, the terms of which are developed and agreed to by both the M+C organization and the relevant provider.

(c) *Failure to comply.* If CMS determines, after giving notice and opportunity for hearing, that an M+C organization has failed to make payments in accordance with paragraph (a) of this section, CMS may provide—

(1) For direct payment of the sums owed to providers, or M+C private fee-for-service plan enrollees; and

(2) For appropriate reduction in the amounts that would otherwise be paid to the organization, to reflect the amounts of the direct payments and the cost of making those payments.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000]

§ 422.521 Effective date of new significant regulatory requirements.

CMS will not implement, other than at the beginning of a calendar year, requirements under this part that impose a new significant cost or burden on M+C organizations or plans, unless a different effective date is required by statute.

[68 FR 50858, Aug. 22, 2003]

§ 422.524 Special rules for RFB societies.

In order to participate as an M+C organization, an RFB society—

(a) May not impose any limitation on membership based on any factor related to health status; and

(b) Must offer, in addition to the M+C RFB plan, health coverage to individuals who are members of the church or convention or group of churches with which the society is affiliated, but who are not entitled to receive benefits from the Medicare program.

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

SOURCE: 63 FR 35067, June 26, 1998, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to subpart L appear at 63 FR 35106, June 26, 1998.

§ 422.550 General provisions.

(a) *What constitutes change of ownership*—(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a change of ownership.

(2) *Asset Sale.* Transfer of title and property to another party constitutes change of ownership.

(3) *Corporation.* (i) The merger of the M+C organization's corporation into another corporation or the consolidation of the M+C organization with one or more other corporations, resulting in a new corporate body, constitutes a change of ownership.

(ii) Transfer of corporate stock or the merger of another corporation into the M+C organization's corporation, with the M+C organization surviving, does not ordinarily constitute change of ownership.

(b) *Advance notice requirement.* (1) An M+C organization that has a Medicare contract in effect and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The M+C organization

must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) If the M+C organization fails to give CMS the required notice timely, it continues to be liable for capitation payments that CMS makes to it on behalf of Medicare enrollees after the date of change of ownership.

(c) *Novation agreement defined.* A novation agreement is an agreement among the current owner of the M+C organization, the prospective new owner, and CMS—

(1) That is embodied in a document executed and signed by all three parties;

(2) That meets the requirements of §422.552; and

(3) Under which CMS recognizes the new owner as the successor in interest to the current owner's Medicare contract.

(d) *Effect of change of ownership without novation agreement.* Except to the extent provided in paragraph (b)(2) of this section, the effect of a change of ownership without a novation agreement is that—

(1) The existing contract becomes invalid; and

(2) If the new owner wishes to participate in the Medicare program, it must apply for, and enter into, a contract in accordance with subpart K of this part.

(e) *Effect of change of ownership with novation agreement.* If the M+C organization submits a novation agreement that meets the requirements of §422.552, and CMS signs it, the new owner becomes the successor in interest to the current owner's Medicare contract.

[60 FR 45681, Sept. 1, 1995. Redesignated and amended at 63 FR 35067, 35106, June 26, 1998; 63 FR 52614, Oct. 1, 1998; 65 FR 40328, June 29, 2000]

§422.552 Novation agreement requirements.

(a) *Conditions for CMS approval of a novation agreement.* HFCA approves a novation agreement if the following conditions are met:

(1) *Advance notification.* The M+C organization notifies CMS at least 60 days before the date of the proposed change of ownership. The M+C organization also provides CMS with updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) *Advance submittal of agreement.* The M+C organization submits to CMS, at least 30 days before the proposed change of ownership date, three signed copies of the novation agreement containing the provisions specified in paragraph (b) of this section, and one copy of other relevant documents required by CMS.

(3) *CMS's determination.* CMS determines that—

(i) The proposed new owner is in fact a successor in interest to the contract;

(ii) Recognition of the new owner as a successor in interest to the contract is in the best interest of the Medicare program; and

(iii) The successor organization meets the requirements to qualify as an M+C organization under subpart J of this part.

(b) *Provisions of a novation agreement.* (1) *Assumption of contract obligations.* The new owner must assume all obligations under the contract.

(2) *Waiver of right to reimbursement.* The previous owner must waive its rights to reimbursement for covered services furnished during the rest of the current contract period.

(3) *Guarantee of performance.* (i) The previous owner must guarantee performance of the contract by the new owner during the contract period; or

(ii) The new owner must post a performance bond that is satisfactory to CMS.

(4) *Records access.* The previous owner must agree to make its books and records and other necessary information available to the new owner and to CMS to permit an accurate determination of costs for the final settlement of the contract period.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38079, July 15, 1993; 60 FR 45681, Sept. 1, 1995. Redesignated and amended at 63 FR 35067, 35106, June 26, 1998]

§ 422.553 Effect of leasing of an M+C organization's facilities.

(a) *General effect of leasing.* If an M+C organization leases all or part of its facilities to another entity, the other entity does not acquire M+C organization status under section 1876 of the Act.

(b) *Effect of lease of all facilities.* (1) If an M+C organization leases all of its facilities to another entity, the contract terminates.

(2) If the other entity wishes to participate in Medicare as an M+C organization, it must apply for and enter into a contract in accordance with subpart L of this part.

(c) *Effect of partial lease of facilities.* If the M+C organization leases part of its facilities to another entity, its contract with CMS remains in effect while CMS surveys the M+C organization to determine whether it continues to be in compliance with the applicable requirements and qualifying conditions specified in subpart K of this part.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45681, Sept. 1, 1995. Redesignated and amended at 63 FR 35067, 35106, June 26, 1998]

Subpart M—Grievances, Organization Determinations and Appeals

SOURCE: 63 FR 35107, June 26, 1998, unless otherwise noted.

§ 422.560 Basis and scope.

(a) *Statutory basis.* (1) Section 1852(f) of the Act provides that an M+C organization must establish meaningful grievance procedures.

(2) Section 1852(g) of the Act establishes requirements that an M+C organization must meet concerning organization determinations and appeals.

(b) *Scope.* This subpart sets forth—

(1) Requirements for M+C organizations with respect to grievance procedures, organization determinations, and appeal procedures.

(2) The rights of M+C enrollees with respect to organization determinations, and grievance and appeal procedures.

(3) The rules concerning notice of noncoverage of inpatient hospital care.

(4) The rules that apply when an M+C enrollee requests immediate QIO review of a determination that he or she no longer needs inpatient hospital care.

§ 422.561 Definitions.

As used in this subpart, unless the context indicates otherwise—

Appeal means any of the procedures that deal with the review of adverse organization determinations on the health care services the enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service, as defined under §422.566(b). These procedures include reconsiderations by the M+C organization, and if necessary, an independent review entity, hearings before ALJs, review by the Departmental Appeals Board (DAB), and judicial review.

Authorized representative means an individual authorized by an enrollee, or under State law, to act on his or her behalf in obtaining an organization determination or in dealing with any of the levels of the appeal process, subject to the rules described in 20 CFR part 404, subpart R, unless otherwise stated in this subpart.

Enrollee means an M+C eligible individual who has elected an M+C plan offered by an M+C organization, or his or her authorized representative.

Grievance means any complaint or dispute, other than one that constitutes an organization determination, expressing dissatisfaction with any aspect of an M+C organization's or provider's operations, activities, or behavior, regardless of whether remedial action is requested.

Physician has the meaning given the term in section 1861(r) of the Act.

[63 FR 35067, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 68 FR 16667, Apr. 4, 2003]

§ 422.562 General provisions.

(a) *Responsibilities of the M+C organization.* (1) An M+C organization, with respect to each M+C plan that it offers, must establish and maintain—

(i) A grievance procedure as described in §422.564 for addressing issues

that do not involve organization determinations;

(ii) A procedure for making timely organization determinations;

(iii) Appeal procedures that meet the requirements of this subpart for issues that involve organization determinations; and

(2) An M+C organization must ensure that all enrollees receive written information about the—

(i) Grievance and appeal procedures that are available to them through the M+C organization; and

(ii) Complaint process available to the enrollee under the QIO process as set forth under section 1154(a)(14) of the Act.

(3) In accordance with subpart K of this part, if the M+C organization delegates any of its responsibilities under this subpart to another entity or individual through which the organization provides health care services, the M+C organization is ultimately responsible for ensuring that the entity or individual satisfies the relevant requirements of this subpart.

(b) *Rights of M+C enrollees.* In accordance with the provisions of this subpart, enrollees have the following rights:

(1) The right to have grievances between the enrollee and the M+C organization heard and resolved, as described in §422.564.

(2) The right to a timely organization determination, as provided under §422.566.

(3) The right to request an expedited organization determination, as provided under §422.570.

(4) If dissatisfied with any part of an organization determination, the following appeal rights:

(i) The right to a reconsideration of the adverse organization determination by the M+C organization, as provided under §422.578.

(ii) The right to request an expedited reconsideration, as provided under §422.584.

(iii) If, as a result of a reconsideration, an M+C organization affirms, in whole or in part, its adverse organization determination, the right to an automatic reconsidered determination made by an independent, outside entity contracted by CMS, as provided in §422.592.

(iv) The right to an ALJ hearing if the amount in controversy is $100 or more, as provided in §422.600.

(v) The right to request DAB review of the ALJ hearing decision, as provided in §422.608.

(vi) The right to judicial review of the hearing decision if the amount in controversy is $1000 or more, as provided in §422.612.

(c) *Limits on when this subpart applies.* (1) If an enrollee receives immediate QIO review (as provided in §422.622) of a determination of noncoverage of inpatient hospital care—

(i) The enrollee is not entitled to review of that issue by the M+C organization; and

(ii) The QIO review decision is subject only to the appeal procedures set forth in part 473 of this chapter.

(2) If an enrollee has no further liability to pay for services that were furnished by an M+C organization, a determination regarding these services is not subject to appeal.

(d) *When other regulations apply.* Unless this subpart provides otherwise, the regulations in 20 CFR, part 404, subparts J and R (covering, respectively, the administrative review and hearing process and representation of parties under title II of the Act), apply under this subpart to the extent they are appropriate.

[63 FR 35067, June 26, 1998, as amended at 65 FR 40329, June 29, 2000]

§422.564 Grievance procedures.

(a) *General rule.* Each M+C organization must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the organization or any other entity or individual through which the organization provides health care services under any M+C plan it offers.

(b) *Distinguished from appeals.* Grievance procedures are separate and distinct from appeal procedures, which address organization determinations as defined in §422.566(b). Upon receiving a complaint, an M+C organization must promptly determine and inform the enrollee whether the complaint is subject to its grievance procedures or its appeal procedures.

(c) *Distinguished from the quality improvement organization (QIO) complaint process.* Under section 1154(a)(14) of the Act, the QIO must review beneficiaries' written complaints about the quality of services they have received under the Medicare program. This process is separate and distinct from the grievance procedures of the M+C organization. For quality of care issues, an enrollee may file a grievance with the M+C organization; file a written complaint with the QIO, or both. For any complaint submitted to a QIO, the M+C organization must cooperate with the QIO in resolving the complaint.

(d) *Expedited grievances.* An M+C organization must respond to an enrollee's grievance within 24 hours if:

(1) The complaint involves an M+C organization's decision to invoke an extension relating to an organization determination or reconsideration.

(2) The complaint involves an M+C organization's refusal to grant an enrollee's request for an expedited organization determination under §422.570 or reconsideration under §422.584.

(e) *Recordkeeping.* The M+C organization must have an established process to track and maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the M+C organization notified the enrollee of the disposition.

[68 FR 16667, Apr. 4, 2003]

§422.566 Organization determinations.

(a) *Responsibilities of the M+C organization.* Each M+C organization must have a procedure for making timely organization determinations (in accordance with the requirements of this subpart) regarding the benefits an enrollee is entitled to receive under an M+C plan, including basic benefits as described under §422.100(c)(1) and mandatory and optional supplemental benefits as described under §422.102, and the amount, if any, that the enrollee is required to pay for a health service. The M+C organization must have a standard procedure for making determinations, in accordance with §422.568, and an expedited procedure for situations in which applying the standard procedure could seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with §§422.570 and 422.572.

(b) *Actions that are organization determinations.* An organization determination is any determination made by an M+C organization with respect to any of the following:

(1) Payment for temporarily out of the area renal dialysis services, emergency services, post-stabilization care, or urgently needed services.

(2) Payment for any other health services furnished by a provider other than the M+C organization that the enrollee believes—

(i) Are covered under Medicare; or

(ii) If not covered under Medicare, should have been furnished, arranged for, or reimbursed by the M+C organization.

(3) The M+C organization's refusal to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the M+C organization.

(4) Discontinuation of a service if the enrollee believes that continuation of the services is medically necessary.

(5) Failure of the M+C organization to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or to provide the enrollee with timely notice of an adverse determination, such that a delay would adversely affect the health of the enrollee.

(c) *Who can request an organization determination.* (1) Those individuals or entities who can request an organization determination are—

(i) The enrollee (including his or her authorized representative);

(ii) Any provider that furnishes, or intends to furnish, services to the enrollee; or

(iii) The legal representative of a deceased enrollee's estate.

(2) Those who can request an expedited determination are—

(i) An enrollee (including his or her authorized representative); or

(ii) A physician (regardless of whether the physician is affiliated with the M+C organization).

[63 FR 35067, June 26, 1998, as amended at 65 FR 40329, June 29, 2000; 68 FR 50858, Aug. 22, 2003]

§422.568 Standard timeframes and notice requirements for organization determinations.

(a) *Timeframe for requests for service.* When a party has made a request for a service, the M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination. The M+C organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). When the M+C organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension. The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(b) *Timeframe for requests for payment.* The M+C organization must process requests for payment according to the "prompt payment" provisions set forth in §422.520.

(c) *Written notification by practitioners.* At each patient encounter with an M+C enrollee, a practitioner must notify the enrollee of his or her right to receive, upon request, a detailed written notice from the M+C organization regarding the enrollee's services, consistent with paragraph (d) of this section. The practitioner's notification must—

(1) Provide the enrollee with the information necessary to contact the M+C organization; and

(2) Comply with any other requirements specified by CMS.

(d) *Written notice for M+C organization denials.* If an enrollee requests an M+C organization to provide a detailed notice of a practitioner's decision to deny a service in whole or in part, or if an M+C organization decides to deny service or payment in whole or in part, it must give the enrollee written notice of the determination.

(e) *Form and content of the M+C organization notice.* The notice of any denial under paragraph (d) of this section must—

(1) Use approved notice language in a readable and understandable form;

(2) State the specific reasons for the denial;

(3) Inform the enrollee of his or her right to a reconsideration;

(4)(i) For service denials, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeal process; and

(ii) For payment denials, describe the standard reconsideration process and the rest of the appeal process; and

(5) Comply with any other notice requirements specified by CMS.

(f) *Effect of failure to provide timely notice.* If the M+C organization fails to provide the enrollee with timely notice of an organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

[65 FR 40329, June 29, 2000]

§422.570 Expediting certain organization determinations.

(a) *Request for expedited determination.* An enrollee or a physician (regardless of whether the physician is affiliated with the M+C organization) may request that an M+C organization expedite an organization determination involving the issues described in §422.566(b)(3) and (b)(4). (This does not include requests for payment of services already furnished.)

(b) *How to make a request.* (1) To ask for an expedited determination, an enrollee or a physician must submit an oral or written request directly to the M+C organization or, if applicable, to the entity responsible for making the determination, as directed by the M+C organization.

(2) A physician may provide oral or written support for a request for an expedited determination.

(c) *How the M+C organization must process requests.* The M+C organization

must establish and maintain the following procedures for processing requests for expedited determinations:

(1) Establish an efficient and convenient means for individuals to submit oral or written requests. The M+C organization must document all oral requests in writing and maintain the documentation in the case file.

(2) Promptly decide whether to expedite a determination, based on the following requirements:

(i) For a request made by an enrollee the M+C organization must provide an expedited determination if it determines that applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a physician, the M+C organization must provide an expedited determination if the physician indicates that applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If an M+C organization denies a request for expedited determination, it must take the following actions:

(1) Automatically transfer a request to the standard timeframe and make the determination within the 14-day timeframe established in §422.568 for a standard determination. The 14-day period begins with the day the M+C organization receives the request for expedited determination.

(2) Give the enrollee prompt oral notice of the denial and subsequently deliver, within 3 calendar days, a written letter that—

(i) Explains that the M+C organization will process the request using the 14-day timeframe for standard determinations;

(ii) Informs the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision not to expedite; and

(iii) Informs the enrollee of the right to resubmit a request for an expedited determination with any physician's support; and

(iv) Provides instructions about the grievance process and its timeframes.

(e) *Action on accepted request for expedited determination.* If an M+C organization grants a request for expedited determination, it must make the determination and give notice in accordance with §422.572.

(f) *Prohibition of punitive action.* An M+C organization may not take or threaten to take any punitive action against a physician acting on behalf or in support of an enrollee in requesting an expedited determination.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40329, June 29, 2000]

§422.572 Timeframes and notice requirements for expedited organization determinations.

(a) *Timeframe.* Except as provided in paragraph (b) of this section, an M+C organization that approves a request for expedited determination must make its determination and notify the enrollee (and the physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

(b) *Extensions.* The M+C organization may extend the 72-hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). When the M+C organization extends the deadline, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension. The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(c) *Confirmation of oral notice.* If the M+C organization first notifies an enrollee of its expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(d) *How the M+C organization must request information from noncontract providers.* If the M+C organization must receive medical information from noncontract providers, the M+C organization must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited organization determination. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the M+C organization in meeting the required timeframe. Regardless of whether the M+C organization must request information from noncontract providers, the M+C organization is responsible for meeting the timeframe and notice requirements of this section.

(e) *Content of the notice of expedited determination.* (1) The notice of any expedited determination must state the specific reasons for the determination in understandable language.

(2) If the determination is not completely favorable to the enrollee, the notice must—

(i) Inform the enrollee of his or her right to a reconsideration;

(ii) Describe both the standard and expedited reconsideration processes, including the enrollee's right to request, and conditions for obtaining, an expedited reconsideration, and the rest of the appeal process; and

(iii) Comply with any other requirements specified by CMS.

(f) *Effect of failure to provide a timely notice.* If the M+C organization fails to provide the enrollee with timely notice of an expedited organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40329, June 29, 2000]

§422.574 Parties to the organization determination.

The parties to the organization determination are—

(a) The enrollee (including his or her authorized representative);

(b) An assignee of the enrollee (that is, a physician or other provider who has furnished a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service);

(c) The legal representative of a deceased enrollee's estate; or

(d) Any other provider or entity (other than the M+C organization) determined to have an appealable interest in the proceeding.

§422.576 Effect of an organization determination.

The organization determination is binding on all parties unless it is reconsidered under §§422.578 through 422.596 or is reopened and revised under §422.616.

§422.578 Right to a reconsideration.

Any party to an organization determination (including one that has been reopened and revised as described in §422.616) may request that the determination be reconsidered under the procedures described in §422.582, which address requests for a standard reconsideration. An enrollee or physician (acting on behalf of an enrollee) may request an expedited reconsideration as described in §422.584.

§422.580 Reconsideration defined.

A reconsideration consists of a review of an adverse organization determination, the evidence and findings upon which it was based, and any other evidence the parties submit or the M+C organization or CMS obtains.

§422.582 Request for a standard reconsideration.

(a) *Method and place for filing a request.* A party to an organization determination must ask for a reconsideration of the determination by filing a written request with—

(1) The M+C organization that made the organization determination;

(2) An SSA office; or

(3) In the case of a qualified railroad retirement beneficiary, an RRB office.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a party must file a request for a reconsideration within 60 calendar days from the date of the notice of the organization determination. If the SSA or RRB receives a request, it forwards the request to the M+C organization for its reconsideration. The

timeframe within which the organization must conduct its review begins when it receives the request.

(c) *Extending the time for filing a request*—(1) *General rule.* If a party shows good cause, the M+C organization may extend the timeframe for filing a request for reconsideration.

(2) *How to request an extension of timeframe.* If the 60-day period in which to file a request for a reconsideration has expired, a party to the organization determination may file a request for reconsideration with the M+C organization, SSA, or an RRB office. If SSA or RRB receives a request, it forwards the request to the M+C organization for its reconsideration. The request for reconsideration and to extend the timeframe must—

(i) Be in writing; and

(ii) State why the request for reconsideration was not filed on time.

(d) *Parties to the reconsideration.* The parties to the reconsideration are the parties to the organization determination, as described in §422.574, and any other provider or entity (other than the M+C organization) whose rights with respect to the organization determination may be affected by the reconsideration, as determined by the entity that conducts the reconsideration.

(e) *Withdrawing a request.* The party who files a request for reconsideration may withdraw it by filing a written request for withdrawal at one of the places listed in paragraph (a) of this section.

§422.584 Expediting certain reconsiderations.

(a) *Who may request an expedited reconsideration.* An enrollee or a physician (regardless of whether he or she is affiliated with the M+C organization) may request that an M+C organization expedite a reconsideration of a determination that involves the issues described in §422.566(b)(3) and (b)(4). (This does not include requests for payment of services already furnished.)

(b) *How to make a request.* (1) To ask for an expedited reconsideration, an enrollee or a physician acting on behalf of an enrollee must submit an oral or written request directly to the M+C organization or, if applicable, to the entity responsible for making the reconsideration, as directed by the M+C organization.

(2) A physician may provide oral or written support for a request for an expedited reconsideration.

(c) *How the M+C organization must process requests.* The M+C organization must establish and maintain the following procedures for processing requests for expedited reconsiderations:

(1) *Handling of requests.* The M+C organization must establish an efficient and convenient means for individuals to submit oral or written requests, document all oral requests in writing, and maintain the documentation in the case file.

(2) *Prompt decision.* Promptly decide on whether to expedite the reconsideration or follow the timeframe for standard reconsideration based on the following requirements:

(i) For a request made by an enrollee, the M+C organization must provide an expedited reconsideration if it determines that applying the standard timeframe for reconsidering a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a physician, the M+C organization must provide an expedited reconsideration if the physician indicates that applying the standard timeframe for conducting a reconsideration could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If an M+C organization denies a request for expedited reconsideration, it must take the following actions:

(1) Automatically transfer a request to the standard timeframe and make the determination within the 30-day timeframe established in §422.590(a). The 30-day period begins the day the M+C organization receives the request for expedited reconsideration.

(2) Give the enrollee prompt oral notice, and subsequently deliver, within 3 calendar days, a written letter that—

(i) Explains that the M+C organization will process the enrollee's request using the 30-day timeframe for standard reconsiderations;

(ii) Informs the enrollee of the right to file a grievance if he or she disagrees with the organization's decision not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited reconsideration with any physician's support; and

(iv) Provides instructions about the grievance process and its timeframes.

(e) *Action following acceptance of a request.* If an M+C organization grants a request for expedited reconsideration, it must conduct the reconsideration and give notice in accordance with §422.590(d).

(f) *Prohibition of punitive action.* An M+C organization may not take or threaten to take any punitive action against a physician acting on behalf or in support of an enrollee in requesting an expedited reconsideration.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40330, June 29, 2000]

§422.586 Opportunity to submit evidence.

The M+C organization must provide the parties to the reconsideration with a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. In the case of an expedited reconsideration, the opportunity to present evidence is limited by the short timeframe for making a decision. Therefore, the M+C organization must inform the parties of the conditions for submitting the evidence.

§422.590 Timeframes and responsibility for reconsiderations.

(a) *Standard reconsideration: Request for services.* (1) If the M+C organization makes a reconsidered determination that is completely favorable to the enrollee, the M+C organization must issue the determination (and effectuate it in accordance with §422.618(a)) as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration. The M+C organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). When the M+C organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension. For extensions, the M+C organization must issue and effectuate its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(2) If the M+C organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by CMS as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration (or no later than the expiration of an extension described in paragraph (a)(1) of this section). The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(b) *Standard reconsideration: Request for payment.* (1) If the M+C organization makes a reconsidered determination that is completely favorable to the enrollee, the M+C organization must issue its reconsidered determination to the enrollee (and effectuate it in accordance with §422.618(a)) no later than 60 calendar days from the date it receives the request for a standard reconsideration.

(2) If the M+C organization affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by CMS no later than 60 calendar days from the date it receives the request for a standard reconsideration. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(c) *Effect of failure to meet timeframe for standard reconsideration.* If the M+C

organization fails to provide the enrollee with a reconsidered determination within the timeframes specified in paragraph (a) or paragraph (b) of this section, this failure constitutes an affirmation of its adverse organization determination, and the M+C organization must submit the file to the independent entity in the same manner as described under paragraphs (a)(2) and (b)(2) of this section.

(d) *Expedited reconsideration*—(1) *Timeframe.* Except as provided in paragraph (d)(2) of this section, an M+C organization that approves a request for expedited reconsideration must complete its reconsideration and give the enrollee (and the physician involved, as appropriate) notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request.

(2) *Extensions.* The M+C organization may extend the 72-hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). When the M+C organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension. The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension.

(3) *Confirmation of oral notice.* If the M+C organization first notifies an enrollee of a completely favorable expedited reconsideration, it must mail written confirmation to the enrollee within 3 calendar days.

(4) *How the M+C organization must request information from noncontract providers.* If the M+C organization must receive medical information from noncontract providers, the M+C organization must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited reconsideration. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the M+C organization in meeting the required timeframe. Regardless of whether the M+C organization must request information from noncontract providers, the M+C organization is responsible for meeting the timeframe and notice requirements.

(5) *Affirmation of an adverse expedited organization determination.* If, as a result of its reconsideration, the M+C organization affirms, in whole or in part, its adverse expedited organization determination, the M+C organization must submit a written explanation and the case file to the independent entity contracted by CMS as expeditiously as the enrollee's health condition requires, but not later than within 24 hours of its affirmation. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(e) *Notification of enrollee.* If the M+C organization refers the matter to the independent entity as described under this section, it must concurrently notify the enrollee of that action.

(f) *Failure to meet timeframe for expedited reconsideration.* If the M+C organization fails to provide the enrollee with the results of its reconsideration within the timeframe described in paragraph (d) of this section, this failure constitutes an adverse reconsidered determination, and the M+C organization must submit the file to the independent entity within 24 hours of expiration of the timeframe set forth in paragraph (d) of this section.

(g) *Who must reconsider an adverse organization determination.* (1) A person or persons who were not involved in making the organization determination must conduct the reconsideration.

(2) When the issue is the M+C organization's denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsidered determination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsidered

determination need not, in all cases, be of the same specialty or subspecialty as the treating physician.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40330, June 29, 2000]

§422.592 Reconsideration by an independent entity.

(a) When the M+C organization affirms, in whole or in part, its adverse organization determination, the issues that remain in dispute must be reviewed and resolved by an independent, outside entity that contracts with CMS.

(b) The independent outside entity must conduct the review as expeditiously as the enrollee's health condition requires but must not exceed the deadlines specified in the contract.

(c) When the independent entity conducts a reconsideration, the parties to the reconsideration are the same parties listed in §422.582(d) who qualified during the M+C organization's reconsideration, with the addition of the M+C organization.

§422.594 Notice of reconsidered determination by the independent entity.

(a) *Responsibility for the notice.* When the independent entity makes the reconsidered determination, it is responsible for mailing a notice of its reconsidered determination to the parties and for sending a copy to CMS.

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the entity's decisions in understandable language;

(2) If the reconsidered determination is adverse (that is, does not completely reverse the M+C organization's adverse organization determination), inform the parties of their right to an ALJ hearing if the amount in controversy is $100 or more;

(3) Describe the procedures that a party must follow to obtain an ALJ hearing; and

(4) Comply with any other requirements specified by CMS.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40330, June 29, 2000]

§422.596 Effect of a reconsidered determination.

A reconsidered determination is final and binding on all parties unless a party other than the M+C organization files a request for a hearing under the provisions of §422.602, or unless the reconsidered determination is revised under §422.616.

[65 FR 40331, June 29, 2000]

§422.600 Right to a hearing.

(a) If the amount remaining in controversy is $100 or more, any party to the reconsideration (except the M+C organization) who is dissatisfied with the reconsidered determination has a right to a hearing before an ALJ. The M+C organization does not have the right to request a hearing before an ALJ.

(b) The amount remaining in controversy, which can include any combination of Part A and Part B services, is computed in accordance with §405.740 of this chapter for Part A services and §405.817 of this chapter for Part B services.

(c) If the basis for the appeal is the M+C organization's refusal to provide services, CMS uses the projected value of those services to compute the amount remaining in controversy.

§422.602 Request for an ALJ hearing.

(a) *How and where to file a request.* A party must file a written request for a hearing at one of the places listed in §422.582(a) or with the independent, outside entity. The organizations listed in §422.582(a) forward the request to the independent, outside entity, which is responsible for transferring the case to the appropriate ALJ hearing office.

(b) *When to file a request.* Except when an ALJ extends the timeframe as provided in 20 CFR 404.933(c), a party must file a request for a hearing within 60 days of the date of the notice of a reconsidered determination.

(c) *Parties to a hearing.* The parties to a hearing are the parties to the reconsideration, the M+C organization, and any other person or entity whose rights with respect to the reconsideration may be affected by the hearing, as determined by the ALJ.

(d) *When the amount in controversy is less than $100.* (1) If a request for a hearing clearly shows that the amount in controversy is less than $100, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than $100, he or she discontinues the hearing and does not rule on the substantive issues raised in the appeal.

§ 422.608 Departmental Appeals Board (the Board) review.

Any party to the hearing, including the M+C organization, who is dissatisfied with the ALJ hearing decision, may request that the Board review the ALJ's decision or dismissal. Regulations located at 20 CFR 404.967 through 404.984 regarding SSA Appeals Council Review apply to Board review for matters addressed by this subpart.

[63 FR 35107, June 26, 1998; 63 FR 52614, Oct. 1, 1998]

§ 422.612 Judicial review.

(a) *Review of ALJ's decision.* Any party, including the M+C organization, may request judicial review (upon notifying the other parties) of an ALJ's decision if—

(1) The Board denied the party's request for review; and

(2) The amount in controversy is $1,000 or more.

(b) *Review of Board decision.* Any party, including the M+C organization, may request judicial review (upon notifying the other parties) of the Board decision if it is the final decision of CMS and the amount in controversy is $ 1,000 or more.

(c) *How to request judicial review.* A party must file a civil action in a district court of the United States in accordance with section 205(g) of the Act (see 20 CFR 422.210 for a description of the procedures to follow in requesting judicial review).

[63 FR 35107, June 26, 1998; 63 FR 52614, Oct. 1, 1998, as amended at 65 FR 40331, June 29, 2000]

§ 422.616 Reopening and revising determinations and decisions.

(a) An organization or reconsidered determination made by an M+C organization, a reconsidered determination made by the independent entity described in § 422.592, or the decision of an ALJ or the Board that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in § 405.750 of this chapter.

(b) Reopening may be at the instigation of any party.

(c) The filing of a request for reopening does not relieve the M+C organization of its obligation to make payment or provide services as specified in § 422.618.

(d) Once an entity issues a revised determination or decision, any party may file an appeal.

[63 FR 35107, June 26, 1998; 63 FR 52614, Oct. 1, 1998]

§ 422.618 How an M+C organization must effectuate standard reconsidered determinations or decisions.

(a) *Reversals by the M+C organization*—(1) *Requests for service.* If, on reconsideration of a request for service, the M+C organization completely reverses its organization determination, the organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days after the date the M+C organization receives the request for reconsideration (or no later than upon expiration of an extension described in § 422.590(a)(1)).

(2) *Requests for payment.* If, on reconsideration of a request for payment, the M+C organization completely reverses its organization determination, the organization must pay for the service no later than 60 calendar days after the date the M+C organization receives the request for reconsideration.

(b) *Reversals by the independent outside entity.* (1) *Requests for service.* If, on reconsideration of a request for service, the M+C organization's determination is reversed in whole or in part by the independent outside entity, the M+C organization must authorize the service under dispute within 72 hours from the date it receives notice reversing the determination, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 14 calendar

days from that date. The M+C organization must inform the independent outside entity that the organization has effectuated the decision.

(2) *Requests for payment.* If, on reconsideration of a request for payment, the M+C organization's determination is reversed in whole or in part by the independent outside entity, the M+C organization must pay for the service no later than 30 calendar days from the date it receives notice reversing the organization determination. The M+C organization must inform the independent outside entity that the organization has effectuated the decision.

(c) *Reversals other than by the M+C organization or the independent outside entity.*—(1) *General rule.* If the independent outside entity's determination is reversed in whole or in part by the ALJ, or at a higher level of appeal, the M+C organization must pay for, authorize, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date it receives notice reversing the determination. The M+C organization must inform the independent outside entity that the organization has effectuated the decision or that it has appealed the decision.

(2) *Effectuation exception when the M+C organization files an appeal with the Departmental Appeals Board.* If the M+C organization requests Departmental Appeals Board (the Board) review consistent with §422.608, the M+C organization may await the outcome of the review before it pays for, authorizes, or provides the service under dispute. A M+C organization that files an appeal with the Board must concurrently send a copy of its appeal request and any accompanying documents to the enrollee and must notify the independent outside entity that it has requested an appeal.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40331, June 29, 2000; 68 FR 50858, Aug. 22, 2003]

§422.619 How an M+C organization must effectuate expedited reconsidered determinations.

(a) *Reversals by the M+C organization.* If on reconsideration of an expedited request for service, the M+C organization completely reverses its organization determination, the M+C organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the M+C organization receives the request for reconsideration (or no later than upon expiration of an extension described in §422.590(d)(2)).

(b) *Reversals by the independent outside entity.* If the M+C organization's determination is reversed in whole or in part by the independent outside entity, the M+C organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination. The M+C organization must inform the independent outside entity that the organization has effectuated the decision.

(c) *Reversals other than by the M+C organization or the independent outside entity*—(1) *General rule.* If the independent outside entity's expedited determination is reversed in whole or in part by the ALJ, or at a higher level of appeal, the M+C organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 days from the date it receives notice reversing the determination. The M+C organization must inform the independent outside entity that the organization has effectuated the decision.

(2) *Effectuation exception when the M+C organization files an appeal with the Departmental Appeals Board.* If the M+C organization requests Departmental Appeals Board (the Board) review consistent with §422.608, the M+C organization may await the outcome of the review before it authorizes or provides the service under dispute. A M+C organization that files an appeal with the Board must concurrently send a copy of its appeal request and any accompanying documents to the enrollee and must notify the independent outside entity that it has requested an appeal.

[65 FR 40331, June 29, 2000, as amended at 68 FR 50859, Aug. 22, 2003]

§ 422.620 How M+C enrollees must be notified of noncoverage of inpatient hospital care.

(a) *Enrollee's entitlement.* (1) Where an M+C organization has authorized coverage of the inpatient admission of an enrollee, either directly or by delegation (or the admission constitutes emergency or urgently needed care, as described in §§ 422.2 and 422.113), the M+C organization (or hospital that has been delegated the authority to make the discharge decision) must provide a written notice of noncoverage when—

(i) The beneficiary disagrees with the discharge decision; or

(ii) The M+C organization (or the hospital that has been delegated the authority to make the discharge decision) is not discharging the individual but no longer intends to continue coverage of the inpatient stay.

(2) An enrollee is entitled to coverage until at least noon of the day after such notice is provided. If QIO review is requested under § 422.622, coverage is extended as provided in that section.

(b) *Physician concurrence required.* Before notice of noncoverage is provided, the entity that makes the noncoverage/discharge determination (that is, the hospital by delegation or the M+C organization) must obtain the concurrence of the physician who is responsible for the enrollee's inpatient care.

(c) *Notice to the enrollee.* The written notice of non-coverage must be issued no later than the day before hospital coverage ends. The written notice must include the following elements:

(1) The reason why inpatient hospital care is no longer needed.

(2) The effective date and time of the enrollee's liability for continued inpatient care.

(3) The enrollee's appeal rights.

(4) Additional information specified by CMS.

[68 FR 16667, Apr. 4, 2003]

EFFECTIVE DATE NOTE: At 68 FR 20349, Apr. 4, 2003, § 422.620 was revised. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget

§ 422.622 Requesting immediate QIO review of noncoverage of inpatient hospital care.

(a) *Enrollee's right to review or reconsideration.* (1) An enrollee who wishes to appeal a determination by an M+C organization or hospital that inpatient care is no longer necessary must request immediate QIO review of the determination in accordance with paragraph (b) of this section. An enrollee who requests immediate QIO review may remain in the hospital with no additional financial liability as specified in paragraph (c) of this section.

(2) An enrollee who fails to request immediate QIO review in accordance with the procedures in paragraph (b) of this section may request expedited reconsideration by the M+C organization as described in § 422.584, but the financial liability rules of paragraph (c) of this section do not apply.

(b) *Procedures enrollee must follow.* For the immediate QIO review process, the following rules apply:

(1) The enrollee must submit the request for immediate review—

(i) To the QIO that has an agreement with the hospital under § 466.78 of this chapter;

(ii) In writing or by telephone; and

(iii) By noon of the first working day after he or she receives written notice that the M+C organization or hospital has determined that the hospital stay is no longer necessary.

(2) On the date it receives the enrollee's request, the QIO must notify the M+C organization that the enrollee has filed a request for immediate review.

(3) The M+C organization must supply any information that the QIO requires to conduct its review and must make it available, by phone or in writing, by the close of business of the first full working day immediately following the day the enrollee submits the request for review.

(4) In response to a request from the M+C organization, the hospital must submit medical records and other pertinent information to the QIO by close of business of the first full working day immediately following the day the organization makes its request.

(5) The QIO must solicit the views of the enrollee who requested the immediate QIO review.

(6) The QIO must make a determination and notify the enrollee, the hospital, and the M+C organization by close of business of the first working day after it receives all necessary information from the hospital, or the organization, or both.

(c) *Liability for hospital costs*—(1) *When the M+C organization determines that hospital services are not, or are no longer, covered.* (i) Except as provided in paragraph (c)(1)(ii) of this section, if the M+C organization authorized coverage of the inpatient admission directly or by delegation (or the admission constitutes emergency or urgently needed care, as described in §§ 422.2 and 422.112(c)), the organization continues to be financially responsible for the costs of the hospital stay when a timely appeal is filed under paragraph (a)(1) of this section until noon of the calendar day following the day the QIO notifies the enrollee of its review determination. If coverage of the hospital admission was never approved by the M+C organization (or the admission does not constitute emergency or urgently needed care, as described in §§ 422.2 and 422.112(c)), the M+C organization is liable for the hospital costs only if it is determined on appeal that the hospital stay should have been covered under the M+C plan.

(ii) The hospital may not charge the M+C organization (or the enrollee) if—

(A) It was the hospital (acting on behalf of the enrollee) that filed the request for immediate QIO review; and

(B) The QIO upholds the noncoverage determination made by the M+C organization.

(2) *When the hospital determines that hospital services are no longer required.* If the hospital determines that inpatient hospital services are no longer necessary, and the enrollee could not reasonably be expected to know that the services would not be covered, the hospital may not charge the enrollee for inpatient services received before noon of the calendar day following the day the QIO notifies the enrollee of its review determination.

[63 FR 35107, June 26, 1998; 63 FR 52614, Oct. 1, 1998]

§ 422.624 Notifying enrollees of termination of provider services.

(a) *Applicability.* (1) For purposes of §§ 422.624 and 422.626, the term provider includes home health agencies (HHAs), skilled nursing facilities (SNFs), and comprehensive outpatient rehabilitation facilities (CORFs).

(2) *Termination of service defined.* For purposes of this section and § 422.626, a termination of service is the discharge of an enrollee from covered provider services, or discontinuation of covered provider services, when the enrollee has been authorized by the M+C organization, either directly or by delegation, to receive an ongoing course of treatment from that provider. Termination includes cessation of coverage at the end of a course of treatment preauthorized in a discrete increment, regardless of whether the enrollee agrees that such services should end.

(b) *Advance written notification of termination.* Prior to any termination of service, the provider of the service must deliver valid written notice to the enrollee of the M+C organization's decision to terminate services. The provider must use a standardized notice, required by the Secretary, in accordance with the following procedures—

(1) *Timing of notice.* The provider must notify the enrollee of the M+C organization's decision to terminate covered services no later than two days before the proposed end of the services. If the enrollee's services are expected to be fewer than two days in duration, the provider should notify the enrollee at the time of admission to the provider. If, in a non-institutional setting, the span of time between services exceeds two days, the notice should be given no later than the next to last time services are furnished.

(2) *Content of the notice.* The standardized termination notice must include the following information:

(i) The date that coverage of services ends.

(ii) The date that the enrollee's financial liability for continued services begins.

(iii) A description of the enrollee's right to a fast-track appeal under § 422.626, including information about how to contact an independent review

entity (IRE), an enrollee's right (but not obligation) to submit evidence showing that services should continue, and the availability of other M+C appeal procedures if the enrollee fails to meet the deadline for a fast-track IRE appeal.

(iv) The enrollee's right to receive detailed information in accordance with § 422.626 (e)(1) and (2).

(v) Any other information required by the Secretary.

(c) *When delivery of notice is valid.*

Delivery of the termination notice is not valid unless—

(1) The enrollee (or the enrollee's authorized representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents; and

(2) The notice is delivered in accordance with paragraph (b)(1) of this section and contains all the elements described in paragraph (b)(2) of this section.

(d) *Financial liability for failure to deliver valid notice.* An M+C organization is financially liable for continued services until 2 days after the enrollee receives valid notice as specified under paragraph (c) of this section. An enrollee may waive continuation of services if he or she agrees with being discharged sooner than 2 days after receiving the notice.

EFFECTIVE DATE NOTE: At 68 FR 20349, Apr. 4, 2003, § 422.624 was added. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget

§ 422.626 Fast-track appeals of service terminations to independent review entities (IREs).

(a) *Enrollee's right to a fast-track appeal of an M+C organization's termination decision.* An enrollee of an M+C organization has a right to a fast-track appeal of an M+C organization's decision to terminate provider services.

(1) An enrollee who desires a fast-track appeal must submit a request for an appeal to an IRE under contract with CMS, in writing or by telephone, by noon of the first day after the day of delivery of the termination notice. If, due to an emergency, the IRE is closed and unable to accept the enrollee's request for a fast-track appeal, the enrollee must file a request by noon of the next day that the IRE is open for business.

(2) When an enrollee fails to make a timely request to an IRE, he or she may request an expedited reconsideration by the M+C organization as described in § 422.584.

(3) If, after delivery of the termination notice, an enrollee chooses to leave a provider or discontinue receipt of covered services on or before the proposed termination date, the enrollee may not later assert fast-track IRE appeal rights under this section relative to the services or expect the services to resume, even if the enrollee requests an appeal before the discontinuation date in the termination notice.

(b) *Coverage of provider services.* Coverage of provider services continues until the date and time designated on the termination notice, unless the enrollee appeals and the IRE reverses the M+C organization's decision. If the IRE's decision is delayed because the M+C organization did not timely supply necessary information or records, the M+C organization is liable for the costs of any additional coverage required by the delayed IRE decision. If the IRE finds that the enrollee did not receive valid notice, coverage of provider services by the M+C organization continues until at least two days after valid notice has been received. Continuation of coverage is not required if the IRE determines that coverage could pose a threat to the enrollee's health or safety.

(c) *Burden of proof.* When an enrollee appeals an M+C organization's decision to terminate services to an IRE, the burden of proof rests with the M+C organization to demonstrate that termination of coverage is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies.

(1) To meet this burden, the M+C organization must supply any and all information that an IRE requires to sustain the M+C organization's termination decision, consistent with paragraph (e) of this section.

(2) The enrollee may submit evidence to be considered by an IRE in making its decision.

(3) The M+C organization or an IRE may require an enrollee to authorize release to the IRE of his or her medical records, to the extent that the records are necessary for the M+C organization to demonstrate the correctness of its decision or for an IRE to determine the appeal.

(d) *Procedures an IRE must follow.* (1) On the date an IRE receives the enrollee's request for an appeal, the IRE must immediately notify the M+C organization and the provider that the enrollee has filed a request for a fast-track appeal, and of the M+C organization's responsibility to submit documentation consistent with paragraph (e)(3) of this section.

(2) When an enrollee requests a fast-track appeal, the IRE must determine whether the provider delivered a valid notice of the termination decision, and whether a detailed notice has been provided, consistent with paragraph (e)(1) of this section.

(3) The IRE must notify CMS about each case in which it determines that improper notification occurs.

(4) Before making its decision, the IRE must solicit the enrollee's views regarding the reason(s) for termination of services as specified in the detailed written notice provided by the M+C organization, or regarding any other reason that the IRE uses as the basis of its review determination.

(5) An IRE must make a decision on an appeal and notify the enrollee, the M+C organization, and the provider of services, by close of business of the day after it receives the information necessary to make the decision. If the IRE does not receive the information needed to sustain an M+C organization's decision to terminate services, it may make a decision on the case based on the information at hand, or it may defer its decision until it receives the necessary information. If the IRE defers its decision, coverage of the services by the M+C organization would continue until the decision is made, consistent with paragraph (b) of this section, but no additional termination notice would be required.

(e) *Responsibilities of the M+C organization.* (1) When an IRE notifies an M+C organization that an enrollee has requested a fast-track appeal, the M+C organization must send a detailed notice to the enrollee by close of business of the day of the IRE's notification. The detailed termination notice must include the following information:

(i) A specific and detailed explanation why services are either no longer reasonable and necessary or are no longer covered.

(ii) A description of any applicable Medicare coverage rule, instruction or other Medicare policy including citations, to the applicable Medicare policy rules, or the information about how the enrollee may obtain a copy of the Medicare policy from the M+C organization.

(iii) Any applicable M+C organization policy, contract provision, or rationale upon which the termination decision was based.

(iv) Facts specific to the enrollee and relevant to the coverage determination that are sufficient to advise the enrollee of the applicability of the coverage rule or policy to the enrollee's case.

(v) Any other information required by CMS.

(2) Upon an enrollee's request, the M+C organization must provide the enrollee a copy of, or access to, any documentation sent to the IRE by the M+C organization, including records of any information provided by telephone. The M+C organization may charge the enrollee a reasonable amount to cover the costs of duplicating the information for the enrollee and/or delivering the documentation to the enrollee. The M+C organization must accommodate such a request by no later than close of business of the first day after the day the material is requested.

(3) Upon notification by the IRE of a fast-track appeal, the M+C organization must supply any and all information, including a copy of the notice sent to the enrollee, that the IRE needs to decide on the appeal. The M+C organization must supply this information as soon as possible, but no later than by close of business of the day that the IRE notifies the M+C organization that an appeal has been received from the

enrollee. The M+C organization must make the information available by phone (with a written record made of what is transmitted in this manner) and/or in writing, as determined by the IRE.

(4) An M+C organization is financially responsible for coverage of services as provided in paragraph (b) of this section, regardless of whether it has delegated responsibility for authorizing coverage or termination decisions to its providers.

(5) If an IRE reverses an M+C organization's termination decision, the M+C organization must provide the enrollee with a new notice consistent with §422.624(b).

(f) *Reconsiderations of IRE decisions.* (1) If the IRE upholds an M+C organization's termination decision in whole or in part, the enrollee may request, no later than 60 days after notification that the IRE has upheld the decision that the IRE reconsider its original decision.

(2) The IRE must issue its reconsidered determination as expeditiously as the enrollee's health condition requires but no later than within 14 days of receipt of the enrollee's request for a reconsideration.

(3) If the IRE reaffirms its decision, in whole or in part, the enrollee may to appeal the IRE's reconsidered determination to an ALJ, the DAB, or a federal court, as provided for under this subpart.

(4) If on reconsideration the IRE determines that coverage of provider services should terminate on a given date, the enrollee is liable for the costs of continued services after that date unless the IRE's decision is reversed on appeal. If the IRE's decision is reversed on appeal, the M+C organization must reimburse the enrollee, consistent with the appealed decision, for the costs of any covered services for which the enrollee has already paid the M+C organization or provider.

EFFECTIVE DATE NOTE: At 68 FR 20349, Apr. 4, 2003, §422.626 was added. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget

Subpart N—Medicare Contract Determinations and Appeals

SOURCE: 63 FR 35113, June 26, 1998, unless otherwise noted.

§422.641 Contract determinations.

This subpart establishes the procedures for making and reviewing the following contract determinations:

(a) A determination that an entity is not qualified to enter into a contract with CMS under Part C of title XVIII of the Act.

(b) A determination to terminate a contract with an M+C organization in accordance with §422.510(a).

(c) A determination not to authorize a renewal of a contract with an M+C organization in accordance with §422.506(b).

§422.644 Notice of contract determination.

(a) When CMS makes a contract determination, it gives the M+C organization written notice.

(b) The notice specifies—

(1) The reasons for the determination; and

(2) The M+C organization's right to request reconsideration.

(c) For CMS-initiated terminations, CMS mails notice 90 days before the anticipated effective date of the termination. For terminations based on initial determinations described at §422.510(a)(5), CMS immediately notifies the M+C organization of its decision to terminate the organization's M+C contract.

(d) When CMS determines that it will not authorize a contract renewal, CMS mails the notice to the M+C organization by May 1 of the current contract year.

§422.646 Effect of contract determination.

The contract determination is final and binding unless—

(a) The determination is reconsidered in accordance with §§422.648 through 422.658;

(b) A timely request for a hearing is filed under §422.662; or

(c) The reconsideration decision is revised as a result of a reopening under §422.696.

§422.648 Reconsideration: Applicability.

(a) Reconsideration is the first step for appealing a contract determination specified in §422.641.

(b) CMS reconsiders the specified determinations if the contract applicant or the M+C organization files a written request in accordance with §422.650.

[63 FR 35113, June 26, 1998, as amended at 65 FR 40331, June 29, 2000]

§422.650 Request for reconsideration.

(a) *Method and place for filing a request.* A request for reconsideration must be made in writing and filed with any CMS office.

(b) *Time for filing a request.* The request for reconsideration must be filed within 15 days from the date of the notice of the initial determination.

(c) *Proper party to file a request.* Only an authorized official of the contract applicant or M+C organization that was the subject of a contract determination may file the request for reconsideration.

(d) *Withdrawal of a request.* The M+C organization or contract applicant who filed the request for a reconsideration may withdraw it at any time before the notice of the reconsidered determination is mailed. The request for withdrawal must be in writing and filed with CMS.

[63 FR 35113, June 26, 1998, as amended at 65 FR 40331, June 29, 2000]

§422.652 Opportunity to submit evidence.

CMS provides the M+C organization or contract applicant and the CMS official or officials who made the contract determination reasonable opportunity, not to exceed the timeframe in which an M+C organization could choose to request a hearing as described at §422.662, to present as evidence any documents or written statements that are relevant and material to the matters at issue.

[65 FR 40332, June 29, 2000]

§422.654 Reconsidered determination.

A reconsidered determination is a new determination that—

(a) Is based on a review of the contract determination, the evidence and findings upon which that was based, and any other written evidence submitted before notice of the reconsidered determination is mailed, including facts relating to the status of the M+C organization subsequent to the contract determination; and

(b) Affirms, reverses, or modifies the initial determination.

§422.656 Notice of reconsidered determination.

(a) CMS gives the M+C organization or contract applicant written notice of the reconsidered determination.

(b) The notice—

(1) Contains findings with respect to the contract applicant's qualifications to enter into, or the M+C organization's qualifications to remain under, a contract with CMS under Part C of title XVIII of the Act;

(2) States the specific reasons for the reconsidered determination; and

(3) Informs the M+C organization or contract applicant of its right to a hearing if it is dissatisfied with the determination.

[63 FR 35113, June 26, 1998, as amended at 65 FR 40332, June 29, 2000]

§422.658 Effect of reconsidered determination.

A reconsidered determination is final and binding unless a request for a hearing is filed in accordance with §422.662 or it is revised in accordance with §422.696.

§422.660 Right to a hearing.

The following parties are entitled to a hearing:

(a) A contract applicant that has been determined in a reconsidered determination to be unqualified to enter into a contract with CMS under Part C of title XVIII of the Act.

(b) An M+C organization whose contract with CMS has been terminated or has not been renewed as a result of a contract determination as provided in §422.641.

[63 FR 35113, June 26, 1998, as amended at 65 FR 40332, June 29, 2000]

§422.662 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be

made in writing and filed by an authorized official of the contract applicant or M+C organization that was the party to the determination under appeal. The request for a hearing must be filed with any CMS office.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 days after the date of the reconsidered determination.

(c) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 422.660;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may be prejudiced by the decision to be rendered at the hearing; and

(3) CMS.

[63 FR 35113, June 26, 1998, as amended at 65 FR 40332, June 29, 2000]

§ 422.664 Postponement of effective date of a contract determination when a request for a hearing with respect to a contract determination is filed timely.

(a) CMS postpones the proposed effective date of the contract determination to terminate a contract with an M+C organization until a hearing decision is reached and affirmed by the Administrator following review under § 422.692 in instances where an M+C organization requests review by the Administrator; and

(b) CMS extends the current contract at the end of the contract period (in the case of a determination not to renew) only—

(1) If CMS finds that an extension of the contract will be consistent with the purpose of this part; and

(2) For such period as CMS and the M+C organization agree.

(c) Exception: A contract terminated in accordance with § 422.510(a)(5) will be immediately terminated and will not be postponed if a hearing is requested.

§ 422.666 Designation of hearing officer.

CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

§ 422.668 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

§ 422.670 Time and place of hearing.

(a) The hearing officer fixes a time and place for the hearing, which is not to exceed 30 days from the receipt of the request for the hearing, and sends written notice to the parties. The notice also informs the parties of the general and specific issues to be resolved and information about the hearing procedure.

(b) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing. The hearing officer may adjourn or postpone the hearing.

(c) The hearing officer will give the parties reasonable notice of any change in time or place of hearing, or of adjournment or postponement.

§ 422.672 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a representative before the Secretary or otherwise prohibited by law.

§ 422.674 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 422.672

may, on behalf of the represented party—

(1) Gives or accepts any notice or request pertinent to the proceedings set forth in this subpart;

(2) Presents evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtains information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§422.676 Conduct of hearing.

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

(d) The hearing officer decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

§422.678 Evidence.

The hearing officer rules on the admissibility of evidence and may admit evidence that would be inadmissible under rules applicable to court procedures.

§422.680 Witnesses.

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties.

§422.682 Discovery.

(a) Prehearing discovery is permitted upon timely request of a party.

(b) A request is timely if it is made before the beginning of the hearing.

(c) A reasonable time for inspection and reproduction of documents is provided by order of the hearing officer.

(d) The hearing officer's order on all discovery matters is final.

§422.684 Prehearing.

The hearing officer may schedule a prehearing conference if he or she believes that a conference would more clearly define the issues.

§422.686 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision has been issued.

§422.688 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.

§422.690 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reversed or modified by the Administrator following review under §422.692, or reopened and revised in accordance with §422.696.

§422.692 Review by the Administrator.

(a) *Request for review by Administrator.* An M+C organization that has received a hearing decision upholding a contract termination determination may request review by the Administrator within 15 days of receiving the hearing decision as provided under §422.690(b).

(b) *Review by the Administrator.* The Administrator shall review the hearing officer's decision, and determine, based upon this decision, the hearing record, and any written arguments submitted by the M+C organization, whether the termination decision should be upheld, reversed, or modified.

(c) *Decision by the Administrator.* The Administrator issues a written decision, and furnishes the decision to the M+C organization requesting review.

§ 422.694 Effect of Administrator's decision.

A decision by the Administrator under section 422.692 is final and binding unless it is reopened and revised in accordance with § 422.696.

§ 422.696 Reopening of contract or reconsidered determination or decision of a hearing officer or the Administrator.

(a) *Initial or reconsidered determination.* CMS may reopen and revise an initial or reconsidered determination upon its own motion within one year of the date of the notice of determination.

(b) *Decision of hearing officer.* A decision of a hearing officer that is unfavorable to any party and is otherwise final may be reopened and revised by the hearing officer upon the officer's own motion within one year of the notice of the hearing decision. Another hearing officer designated by CMS may reopen and revise the decision if the hearing officer who issued the decision is unavailable.

(c) *Decision of Administrator.* A decision by the Administrator that is otherwise final may be reopened and revised by the Administrator upon the Administrator's own motion within one year of the notice of the Administrator's decision.

(d) *Notices.* (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

§ 422.698 Effect of revised determination.

The revision of a contract or reconsidered determination is binding unless a party files a written request for hearing of the revised determination in accordance with § 422.662.

Subpart O—Intermediate Sanctions

SOURCE: 63 FR 35115, June 26, 1998, unless otherwise noted.

§ 422.750 Kinds of sanctions.

(a) The following intermediate sanctions and civil money penalties may be imposed:

(1) Civil money penalties ranging from $10,000 to $100,000 depending upon the violation.

(2) Suspension of enrollment of Medicare beneficiaries.

(3) Suspension of payment to the M+C organization for Medicare beneficiaries who enroll.

(4) Require the M+C organization to suspend all marketing activities to Medicare beneficiaries for the M+C plan subject to the intermediate sanctions.

(b) The enrollment, payment, and marketing sanctions continue in effect until CMS is satisfied that the deficiency on which the determination was based has been corrected and is not likely to recur.

§ 422.752 Basis for imposing sanctions.

(a) *All intermediate sanctions.* For the violations listed below, CMS may impose any of the sanctions specified in § 422.750 on any M+C organization that has a contract in effect. The M+C organization may also be subject to other applicable remedies available under law.

(1) Fails substantially to provide, to an M+C enrollee, medically necessary services that the organization is required to provide (under law or under the contract) to an M+C enrollee, and that failure adversely affects (or is substantially likely to adversely affect) the enrollee.

(2) Imposes on M+C enrollees premiums in excess of the monthly basic and supplemental beneficiary premiums permitted under section 1854 of the Act and subpart G of this part.

(3) Expels or refuses to reenroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that could reasonably be expected to have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services.

(5) Misrepresents or falsifies information that it furnishes—

(i) To CMS; or

(ii) To an individual or to any other entity.

(6) Fails to comply with the requirements of §422.206, which prohibits interference with practitioners' advice to enrollees.

(7) Fails to comply with §422.216, which requires the organization to enforce the limit on balance billing under a private fee-for service plan.

(8) Employs or contracts with an individual who is excluded from participation in Medicare under section 1128 or 1128A of the Act (or with an entity that employs or contracts with such an individual) for the provision of any of the following:

(i) Health care.

(ii) Utilization review.

(iii) Medical social work.

(iv) Administrative services.

(b) *Suspension of enrollment and marketing.* If CMS makes a determination under §422.510(a), CMS may impose the intermediate sanctions in §422.756(c)(1) and (c)(3).

[63 FR 35115, June 26, 1998; 63 FR 52614, Oct. 1, 1998]

§422.756 Procedures for imposing sanctions.

(a) *Notice of Sanction and opportunity to respond*—(1) *Notice of sanction.* Before imposing the intermediate sanctions specified in paragraph (c) of this section CMS—

(i) Sends a written notice to the M+C organization stating the nature and basis of the proposed sanction; and

(ii) Sends the OIG a copy of the notice.

(2) *Opportunity to respond.* CMS allows the M+C organization 15 days from receipt of the notice to provide evidence that it has not committed an act or failed to comply with the requirements described in §422.752, as applicable. CMS may allow a 15-day addition to the original 15 days upon receipt of a written request from the M+C organization. To be approved, the request must provide a credible explanation of why additional time is necessary and be received by CMS before the end of the 15-day period following the date of receipt of the sanction notice. CMS does not grant an extension if it determines that the M+C organization's conduct poses a threat to an enrollee's health and safety.

(b) *Informal reconsideration.* If, consistent with paragraph (a)(2) of this section the M+C organization submits a timely response to CMS's notice of sanction, CMS conducts an informal reconsideration that:

(1) Consists of a review of the evidence by an CMS official who did not participate in the initial decision to impose a sanction; and

(2) Gives the M+C organization a concise written decision setting forth the factual and legal basis for the decision that affirms or rescinds the original determination.

(c) *Specific sanctions.* If CMS determines that an M+C organization has acted or failed to act as specified in §422.752 and affirms this determination in accordance with paragraph (b) of this section, CMS may—

(1) Require the M+C organization to suspend acceptance of applications made by Medicare beneficiaries for enrollment in the sanctioned M+C plan during the sanction period;

(2) In the case of a violation under §422.752(a), suspend payments to the M+C organization for Medicare beneficiaries enrolled in the sanctioned M+C plan during the sanction period; and

(3) Require the M+C organization to suspend all marketing activities for the sanctioned M+C plan to Medicare enrollees.

(d) Effective date and duration of sanctions—(1) *Effective date.* Except as provided in paragraph (d)(2) of this section, a sanction is effective 15 days after the date that the organization is notified of the decision to impose the sanction or, if the M+C organization timely seeks reconsideration under paragraph (b) of this section, on the date specified in the notice of CMS's reconsidered determination.

(2) *Exception.* If CMS determines that the M+C organization's conduct poses a serious threat to an enrollee's health and safety, CMS may make the sanction effective on a date before issuance of CMS's reconsidered determination.

(3) *Duration of sanction.* The sanction remains in effect until CMS notifies the M+C organization that CMS is satisfied that the basis for imposing the

sanction has been corrected and is not likely to recur.

(e) *Termination by CMS.* In addition to or as an alternative to the sanctions described in paragraph (c) of this section, CMS may decline to authorize the renewal of an organization's contract in accordance with §422.506(b)(2) and (b)(3), or terminate the contract in accordance with §422.510.

(f) *Civil money penalties.* (1) If CMS determines that an M+C organization has committed an act or failed to comply with a requirement described in §422.752, CMS notifies the OIG of this determination, and also notifies OIG when CMS reverses or terminates a sanction imposed under this part.

(2) In the case of a violation described in paragraph (a) of §422.752, or a determination under paragraph (b) of §422.752 based upon a violation under §422.510(a)(4) (involving fraudulent or abusive activities), in accordance with the provisions of part 1005 of this title, the OIG may impose civil money penalties on the M+C organization in accordance with part 1005 of this title in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

(3) In the case of a determination under paragraph (b) of §422.752 other than a determination based upon a violation under §422.510(a)(4), in accordance with the provisions of part 1005 of this title, CMS may impose civil money penalties on the M+C organization in the amounts specified in §422.758 in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

[63 FR 35113, June 26, 1998, as amended at 68 FR 50859, Aug. 22, 2003]

§422.758 Maximum amount of civil money penalties imposed by CMS.

(a)If CMS makes a determination under §422.752(b), based on any determination under §422.510(a) except a determination under §422.510(a)(4), CMS may impose civil money penalties in the following amounts:

(1) For the violations listed below, CMS may impose the sanctions specified in §422.750(a)(2), (a)(3), or (a)(4) on any M+C organization that has a contract in effect. The M+C organization may also be subject to other applicable remedies available under law.

(2) For each week that a deficiency remains uncorrected after the week in which the M+C organization receives CMS's notice of the determination—up to $10,000.

(b) If CMS makes a determination under §422.752(b) and §422.756(f)(3), based on a determination under §422.510(a)(1) that an M+C organization has terminated its contract with CMS in a manner other than described under §422.512—$250 per Medicare enrollee from the terminated M+C plan or plans at the time the M+C organization terminated its contract, or $100,000, whichever is greater.

[63 FR 35113, June 26, 1998, as amended at 68 FR 50859, Aug. 22, 2003]

§422.760 Other applicable provisions.

The provisions of section 1128A of the Act (except subsections (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A of the Act.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

Subpart A—General Provisions

Sec.

Subpart B—Certification and Plan of Treatment Requirements